STUDY PROTOCOL

Exploring the perspectives of stroke survivors and healthcare professionals on the use of mobile health to promote physical activity: A qualitative study protocol [version 1; peer review: 1 approved]

Daniel D. Carter, Katie Robinson, John Forbes, Jane C. Walsh, Sara Hayes

1School of Allied Health, University of Limerick, Castletroy, Limerick, Ireland
2Health Research Institute, University of Limerick, Castletroy, Limerick, Ireland
3Ageing Research Centre, University of Limerick, Castletroy, Limerick, Ireland
4Graduate Entry Medical School, University of Limerick, Castletroy, Limerick, Ireland
5School of Psychology, National University of Ireland, Galway, Galway, Ireland

Abstract

Background: Physical inactivity is both the second-highest population attributable risk factor for and a common consequence of stroke. Despite well-documented health benefits associated with physical activity, its levels typically remain below recommended guidelines in stroke survivors. Consequently, calls have been made for novel interventions targeting the promotion of physical activity in stroke survivors. Mobile health is an emerging field which can offer personalised health interventions through mobile and wireless technology. However, a paucity of research has focused on mobile health to promote physical activity in stroke survivors and, more broadly, this field has been criticised for not incorporating the views of stakeholders. This study aims to explore the perspectives of stroke survivors and healthcare professionals on the development of a mobile health intervention for the promotion of physical activity.

Methods: The current study will employ a qualitative descriptive approach using separate, semi-structured focus groups for two key stakeholder groups. Community-dwelling stroke survivors will be recruited through an early supported discharge service for acute stroke and stroke support groups. Healthcare professionals will be recruited through the same early supported discharge service, relevant professional bodies and Twitter. The final number of focus groups will depend on data saturation. Thematic analysis will be conducted using NVivo 12 and findings will be reported in accordance with the Consolidated Criteria for Reporting Qualitative Studies.

Conclusion: This study was granted ethical approval from the HSE Mid-Western Regional Hospital Research Ethics Committee and the Faculty of Education and Health Sciences Research Ethics Committee at the University of Limerick. Output will consist of recommendations for the development of a mobile health intervention aimed at the promotion of physical activity in stroke survivors.
physical activity in stroke survivors. Findings will be disseminated locally through presentations at stroke support groups, as well as internationally through academic conferences and peer-reviewed journals.

**Keywords**
Stroke, physical activity, mHealth, qualitative

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**Corresponding author:** Daniel D. Carter (daniel.carter@ul.ie)

**Author roles:**
- **Carter DD**: Conceptualization, Data Curation, Formal Analysis, Investigation, Methodology, Project Administration, Writing – Original Draft Preparation, Writing – Review & Editing
- **Robinson K**: Conceptualization, Formal Analysis, Methodology, Supervision, Writing – Review & Editing
- **Forbes J**: Conceptualization, Formal Analysis, Funding Acquisition, Methodology, Supervision, Writing – Review & Editing
- **Walsh JC**: Methodology, Writing – Review & Editing
- **Hayes S**: Conceptualization, Formal Analysis, Methodology, Supervision, Writing – Review & Editing

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Introduction

Stroke is a leading cause of death and increase in disability-adjusted life years globally. Developed countries spend an estimated 3% of their healthcare budgets on stroke, a key driver of which is rehabilitation services. Cost of stroke rehabilitation is explained in part by the complex way in which stroke can present, affecting function and reducing participation across a variety of domains, including physical activity (PA).

PA is an overarching term which describes "any bodily movement produced by skeletal muscles that results in energy expenditure"9, whereas exercise is a subsegment of PA described as "planned, structured, and repetitive and has as a final or an intermediate objective the improvement or maintenance of physical fitness"9. Despite the inclusion of both PA and exercise in primary and secondary prevention guidelines7, levels of PA in stroke survivors, including those who are ambulatory, remain low.4 A variety of methods are available for measuring PA, including self-report, direct observation, pedometry and accelerometry4, though objective measures offer greater advantage over self-reported PA data which is frequently overestimated10,11. Meta-analytic evidence demonstrates that daily step count in stroke survivors is estimated at 4355.29. This falls below guidelines for the general population (10000 steps)12 and for adults with chronic illness (6500–8500 steps)13.

Regular and moderate-to-high levels of PA are associated with reduced risk of stroke14 and a large, multi-site case-control study has demonstrated that PA is the second-highest population-attributable risk factor for stroke15. Stroke survivors are at a greater risk of stroke than the general population, with almost a quarter of patients experiencing a recurrent stroke16. The pooled cumulative risk of recurrent stroke is estimated at 11.1% (95% CI, 9.0–13.3) at one year and 39.2% (95% CI, 27.2–51.2) at ten years post stroke17. Recurrent strokes are associated with poorer clinical outcomes, including level of disability and mortality rate, and greater healthcare costs18. Extrapolating the benefits of increasing PA and exercise in the general population to stroke survivors suggests that PA and exercise interventions delivered through stroke rehabilitation may reduce the risk of recurrent stroke19.

Interest in PA by key stakeholders has also been noted. A priority-setting partnership comprised of stroke survivors, caregivers and healthcare professionals (HCPs), using the James Lind Alliance methodology, reached consensus on ten key shared priorities for future research relating to life after stroke. The final priority focused on exploring the role that exercise and fitness programs can play in improving function, quality of life and reducing risk of subsequent stroke20. Further, several of the priorities identified focused on improving stroke-related deficits, including cognition, fatigue, gait, balance and mobility20, each of which, it has been previously argued, has the potential to be improved through exercise and PA21,22.

However, a review by Billinger and colleagues7 concluded that education and tailored exercise counselling have demonstrated only mixed efficacy in increasing PA in stroke survivors. The authors of the review recommend that novel strategies using new technology (e.g. mobile applications (apps) and wearable devices) should be capitalised on in future PA interventions for stroke survivors7. This recommendation with regards incorporating apps and wearables into PA interventions for stroke survivors has been made elsewhere23 and mirrors recommendations from the PA literature more broadly24.

Mobile health (mHealth) is a developing field which aims to promote health through the use of wireless and mobile technology25 and whose ascent is linked to increasing smartphone ownership globally26. It has been recognised for its potential to deliver novel healthcare interventions27 and to bridge systemic gaps28 while offering a level of support not previously available to patients29. Noteworthy for PA interventions, mHealth can also incorporate accelerometry29 which facilitates the capacity for both self-monitoring and objective monitoring by others. While mHealth apps have been deployed in diabetes self-management30 and cardiac rehabilitation31 and have been recommended for use in stroke services32, there has been a paucity of research conducted on the use of mHealth to promote PA in stroke rehabilitation23,33. A recent open-label pilot study on 24 community-dwelling stroke survivors assigned participants to either a mHealth intervention (n=16) or a control group (n=8)34. The intervention group used an existing PA app which had been modified through co-design sessions involving stroke survivors. The findings from the six-week intervention included a significant increase in daily steps, as well as a positive effect on walking time and a reduction in self-reported fatigue34.

Despite the promising findings detailed above, mHealth apps aimed at promoting PA have generally been criticised for their limited use of theory, incorporating only a limited number of behaviour change techniques (BCTs)35–37 and with their implementation being described as “narrow”38 and “far from optimal”39. Further, mHealth in general has been criticised for providing over-engineered solutions without incorporating the views of end-users39.

The Medical Research Council’s (MRC) guidelines for developing complex health interventions emphasises the importance of identifying the existing evidence base39. To this end, a systematic review and meta-synthesis by Carter and colleagues40 was conducted to explore the experience of adults using mHealth for the promotion of PA. However, it identified no studies focusing on the experiences of stroke survivors. Qualitative research is noted to be essential in developing all stages of a digital health intervention41 and reporting guidelines by the World Health Organization describe end-user feedback as an important element in developing mHealth interventions.42 To further advance the evidence base for an intervention to promote PA in stroke survivors, the current study will explore the perspectives of two key stakeholder groups: stroke survivors and HCPs.

Methods

Design

This research will employ a qualitative design to explore stakeholder perspectives on the use of mHealth for the promotion...
of PA. A qualitative descriptive approach was chosen for its ability to offer broad and rich information, as well as straight descriptions of participants’ attitudes toward the development of a potential mHealth-based intervention. This approach is noted for its usefulness in gaining preliminary insight into a topic and in collecting the first-hand experiences of patients and HCPs. The conduct and reporting of this study will be in accordance with the Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist for focus groups to ensure rigor, comprehensiveness and credibility.

Research team roles and prior experience
All focus groups will be moderated, transcribed and analysed by D.C., an occupational therapist and PhD candidate. D.C. has completed training in qualitative research which focused on developing the skills of early-career researchers as part of his graduate studies. It included a focus on developing reflexive skills, strategies for improving credibility during analysis, as well as writing. D.C. also has experience of appraising and synthesising qualitative research. K.R. is a senior lecturer in occupational therapy and an experienced qualitative researcher. K.R. will provide critical feedback throughout the analysis and dissemination stages. S.H. is a lecturer in physiotherapy and an experienced quantitative researcher. S.H., as the principal investigator, has led on the conceptualisation of this research and will contribute to the analysis and dissemination stages. J.F. is an experienced quantitative researcher. S.H., as the principal investigator, has led on the conceptualisation of this research and will contribute to the analysis, particularly with regards health behaviour change.

Recruitment and participants
Community-dwelling stroke survivors and HCPs will be recruited purposively. Previous research suggests that an estimated 80% of themes are identifiable within three to four focus groups and that the modal recommendation for number of individuals participating in a focus group is eight. However, recruitment will continue until data saturation has been reached, as indicated by redundancy in the data and no new themes being generated.

Stroke survivors will be recruited from an early supported discharge service for acute stroke patients associated with a regional hospital in the Mid-West of Ireland and local stroke support groups in the Mid-West and Dublin regions of Ireland. Stroke survivors living in the community and able to voluntarily participate will be sought. However, those with severe impairment following stroke will be excluded as it may preclude an individual’s ability to use mHealth apps and the development of a mHealth intervention for those with more severe impairment is beyond the scope of the current study. Individuals with minimal cognitive and communication impairments are sought to ensure ability to engage in focus group discussions.

HCPs will be recruited through the same acute hospital setting as stroke survivors, as well as two professional bodies (the Association of Occupational Therapists of Ireland and the Irish Society of Chartered Physiotherapists), and Twitter. Representatives from medical, nursing, and the allied health professions will be eligible to attend the focus groups.

All participants must be willing and able to provide informed consent. There is no connection between researchers and participants in either stakeholder group.

Data collection
Focus groups are a popular method of data collection in health research and have previously been used to explore lifestyle beliefs and behaviours as well as the adoption of technology by stroke survivors. They will be used to capitalise on the shared experiences within the two stakeholder groups. A semi-structured topic guide comprised of open-ended questions is typical in qualitative descriptive studies and will support the researcher to remain flexible by adapting questions and expanding on ideas. This method allows participants to build on one another’s comments by developing, undermining and qualifying their statements and generating rich data in the process. Importantly, focus groups do not discriminate against individuals who have difficulty reading or writing and can encourage contributions from those who feel they might have nothing to say or those intimidated by one-to-one interviews.

The power differential between HCPs and patients has been explored previously and, with a view to minimising the effect of this, focus groups with stroke survivors will be conducted separately from those with HCPs to facilitate candid discussion. Each focus group is expected to last one hour and, in instances where scheduling difficulties or non-attendance occurs, one-to-one interviews will be completed using the same topic guide.

Data will be stored in accordance with the University of Limerick’s Data Protection Policy. Participants will be assigned a unique participant number as each focus group is transcribed. A separate, password-protected Excel file will hold participants’ details and their unique participant number on a password protected laptop. Audio files will be deleted after transcription and the research team will only have access to anonymised transcripts. These transcripts will be stored on a password-protected laptop. Transcripts will not be offered to participants. Consent forms will be stored on-site at the School of Allied Health in a locked cabinet. Data will be retained for seven years. After this time, all electronic copies of data will be deleted and all hard copies will be shredded.

Topic guides
Topic guides were developed by reviewing relevant qualitative literature and are available as Extended data. As noted above, a systematic review was conducted to explore the experiences of adults using mHealth for the promotion of PA. Although no studies exploring the experiences of stroke survivors were identified, it did note the central role of motivation. For this reason, behaviour change theory was considered important in
developing the topic guides. Guidelines from the National Institute for Health and Care Excellence (NICE) recommend that interventions targeting behaviour change should incorporate relevant theory and highlight the Capability, Opportunity and Motivation (COM-B) Model developed by Michie and colleagues as part of their Behaviour Change Wheel framework. This model proposes that behaviours arise from an interaction between capability, opportunity, and motivation, and that a successful behaviour change intervention must address deficits related to one or more of those conditions. The COM-B model has previously been applied to guide an exercise intervention in adult stroke survivors and was selected to inform the topic guides for both stakeholder groups. Qualitative studies exploring patient and HCP attitudes towards digital health interventions for blood pressure management and barriers and facilitators to PA in stroke survivors also contributed to the included questions.

The topic guide for stroke survivors will explore their current level of PA in the context of the COM-B model in preparation for asking them to consider using mHealth to promote PA. This topic guide will incorporate a “think aloud” component where participants interact with a mHealth app while saying out loud their thoughts. This strategy was selected to facilitate discussion by making the idea of a mHealth intervention less abstract. Think-aloud strategies have been recommended for engaging end-users in mHealth app development and have been used effectively in exploring patients’ attitudes towards digital health interventions. The app selected for stroke survivors to interact with is “Active 10” by Public Health England. It encourages brisk walking and was selected because it is currently being promoted by general practitioners and public health nurses and because it contains features commonly reported in apps aimed at promoting PA.

The topic guide for HCPs will explore their perspectives on barriers and facilitators to PA in stroke survivors in the context of the COM-B model. Questions specific to HCPs were informed in part by a systematic review exploring barriers and facilitators to mHealth adoption by health professionals. This review identified 179 elements related to barriers and facilitators and separated these into four domains. These domains included mHealth characteristics (e.g. perceived usefulness and ease of use), individual factors (e.g. familiarity with mHealth and technology), external factors related to the human environment (e.g. patients’ attitudes to mHealth), and external factors related to the organisational environment (e.g. workload and human resources).

Analysis
Focus groups will be audio-recorded, transcribed and exported to NVivo (Version 12, QSR International) for analysis by D.C. Thematic analysis was selected for its theoretical flexibility, as well as its ability to generate findings which are accessible to the educated general population, supporting dissemination to HCPs and stroke survivors alike. An iterative approach to analysis will be taken where data collection and analysis occur concurrently to inform one another. The current study will rely on an essentialist/realist paradigm, which assumes a unidirectional relationship between meaning and experience and language, and supports the theorising of participants’ experiences, meanings and realities in a straightforward way. Data will be analysed inductively with codes based on the content of data rather than relying on existing concepts or frameworks. Themes will be identified on a semantic level with a focus on the explicit content of the transcripts. Standard approaches to ensuring trustworthiness will be employed, including engaging in reflexivity through the self-disclosure of biases and assumptions which might influence the interpretation of data, documentation of decisions made throughout the process in the form of an audit trail, and negative case analysis with a view to scrutinising emerging themes against any discrediting data.

The thematic analysis will be carried out in accordance with the six steps outlined by Braun and Clarke. The first step will involve familiarisation with the data. This will be achieved initially through transcription and again through reading and rereading the data. Initial thoughts will be recorded during this process to inform the next step. The second step will involve generating initial codes systematically across the data. All segments of data potentially relevant to the research question will be coded. In the third step, searching for themes will commence. This will involve identifying overlapping codes, with each theme representing a pattern of responses in the data. Step four will involve reviewing potential themes. This will require questioning the boundaries of and judging whether there is sufficient data to support each theme. In step five, clear definitions and names will be established for each theme. The sixth step involves producing the final report. This will be achieved through the preparation of a manuscript which weaves together the themes in a logical and meaningful manner, generating a compelling story of the data drawn from the analysis. Themes will be supported by anonymised quotations from participants.

Ethics approval and consent to participate
Ethical approval has been granted by the HSE Mid-Western Regional Hospital Research Ethics Committee [REC Ref 102/17] and the Faculty of Education and Health Sciences Research Ethics Committee at the University of Limerick [2019_04_04_EHS]. At the start of each focus group, D.C. will review the participant information leaflet with participants. It will be made clear in writing and orally that the current study forms a component of D.C.’s doctoral studies, that participation is voluntary in nature, that the right to withdraw at any time is guaranteed, that data will be stored securely and that participants will not be identifiable in any output generated. Each focus group will only commence when informed consent from all participants is received.

Dissemination
Following the analysis, the findings will be submitted for publication in peer-reviewed journals. They will also be presented at relevant international academic conferences in the areas of mHealth or stroke. The findings will be presented locally to attendees of groups which support stroke survivors.
Conclusion
The current study is being conducted with a view to developing the evidence base for a mHealth intervention to promote PA in stroke survivors. To our knowledge, no prior study has attempted to explore the perspectives of stakeholders on this topic. The project is guided by the development stage of the MRC framework for complex interventions. It follows on from a recently completed systematic review and meta-synthesis exploring the experiences of adults using mHealth for the promotion of PA and recommendations that digital interventions incorporate qualitative research and end-users’ perspectives.

Data availability
Underlying data
No underlying data are associated with this article.

Extended data
Open Science Framework: Exploring the perspectives of stroke survivors and healthcare professionals on the use of mobile health to promote physical activity. https://doi.org/10.17605/OSF.IO/W4JQZ

This project contains the stakeholder topic guides.

Grant information
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The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

References


Reference Source  


70. Lacobucci G: Sedentary lifestyle is putting middle aged health at risk, PHE warns. BMJ. 2017; 358: i3995.  


Reference Source  


Open Peer Review

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Reviewer Report 21 June 2019

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Mary E. Walsh
School of Physiotherapy, Royal College of Surgeons in Ireland (RCSI), Dublin, Ireland

This qualitative protocol is very well written, demonstrates good scientific practice to ensure validity, and is transparent in line with COREQ guidelines.
I would recommend some minor amendments to improve clarity:

Abstract:
The Abstract places much focus on background literature but more detail in the Methods section would be more helpful.

Introduction:
This section is very well laid out and the rationale of the study is clearly explained. More explicit aims and objectives could be specified here.
In paragraph 4, when reference is made to a systematic review the term “has been previously argued” is used. If there is evidence in favour of benefits, this should be stated more clearly.

Methods:

Primary points
- A clearer definition is required with regards to excluding those with “severe impairment”. How will this be assessed and in what domains will impairment be considered?
- Similarly, how will “minimal cognitive and communication impairments” be assessed? As communication and cognitive impairments are very common after stroke and would influence the use of a mobile application, it could be argued that these patient perspectives would be important to capture.
- In the context of this work, the concept of “information power” may be more applicable than “data saturation” in making decisions about sample size. (See Malterud et al. (2016)¹. If you choose to
use “data saturation”, it should be operationalised what saturation is and how it can be measured and defined. (See Francis et al. (2010)².

• While it has been stated that DC will perform analysis, KR will provide critical feedback on analysis and SH will contribute to analysis, the roles of multiple researchers has not been made clear in the Analysis section of the Methods. At what point will feedback be received and will any independent coding be conducted?

Minor points
• Will there be an additional note-taker/co-moderator present at the focus groups and will field notes be made?

• Purposive sampling is described but how will this be conducted for stroke survivors? Will a mix of age, gender, level of disability, place of residence, co-habitation status etc. be sought?

• More detail would be helpful with regard to method of recruitment: Will a gatekeeper be used and how will patients and health professionals in the hospital be approached?

• “There is no connection between researchers and participants” – This may not be the case as researchers are also health professionals and may know participants. This should not preclude participation. If any participants are known to researchers, this can be reported for transparency.

• Has the Topic Guide been piloted or are there plans to pilot it?

• The first question in the Topic Guide (Could you tell me a little about your experience of being treated for your stroke?) may be too broad and lead to much discussion about the acute setting. Perhaps re-focusing on recovery (i.e. Could you tell me a little about your experience of your recovery since your stroke?) would remain open-ended but would provide richer data for the purposes of the research question.

References

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?
Yes

Are the datasets clearly presented in a useable and accessible format?
Yes
**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** Physiotherapy, recovery after stroke.

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.