

1 **The development of a self-management intervention for stroke survivors –**

2 **My Life After Stroke (MLAS)**

3 *This is an Accepted Manuscript of an article published by Taylor & Francis in*
4 *Disability & Rehabilitation on 3rd February 2022, available online:*
5 <http://www.tandfonline.com/10.1080/09638288.2022.2029959>

6 *This is an Accepted Manuscript version of the following article, accepted for*
7 *publication in Disability & Rehabilitation. Vicki L. Johnson, Lindsay Apps, Michelle*
8 *Hadjiconstantinou, Marian E. Carey, Elizabeth Kreit, Ricky Mullis, Jonathan Mant & Melanie*
9 *J. Davieson behalf of the MLAS Development Group (2022): The development of a self-*
10 *management intervention for stroke survivors – My Life After Stroke (MLAS), Disability and*
11 *Rehabilitation. It is deposited under the terms of the Creative Commons Attribution-*
12 *NonCommercial License (<http://creativecommons.org/licenses/by-nc/4.0/>), which*
13 *permits non-commercial re-use, distribution, and reproduction in any medium,*
14 *provided the original work is properly cited."*

15

16

17 **Disability and Rehabilitation**

18 **Funding:**

19 This study is funded by the National Institute for Health Research (NIHR) [Programme
20 Grants for Applied Research (PTC-RP-PG-0213-20001)].

21

22 **IRAS:** 213022

23 Favourable ethical opinion was granted by the West Midlands, South Birmingham Research
24 Ethics Committee on 23rd February 2017 (IRAS 213022).

25

26 **ISRCTN:** 70039829

1 Johnson, VL¹, Apps L^{1,2}, Hadjiconstantinou, M³, Carey ME¹, Kreit E⁴, Mullis R⁴, Mant J⁴,
2 Davies MJ^{3,5} on behalf of the MLAS development group

3 **Correspondence:**

4 Vicki Johnson, Air, IMPACT Team, Leicester Diabetes Centre, University Hospitals of
5 Leicester NHS Trust, Leicester General Hospital, Gwendolen Road, Leicester, LE5 4PW.

6 Email: Vicki.johnson@uhl-tr.nhs.uk

7 Affiliations:

8 ¹Leicester Diabetes Centre, University Hospitals of Leicester NHS Trust, Leicester, UK

9 ²De Montfort University, Leicester, UK

10 ³Diabetes Research Centre, University of Leicester, Leicester, UK

11 ⁴Primary Care Unit, Department of Public Health & Primary Care, University of Cambridge,
12 Cambridge, UK

13 ⁵Leicester Biomedical Research Centre, NIHR, Leicester, UK

14

15

1 **Abstract**

2 ***Purpose***

3 Long-term needs of stroke survivors (especially psychosocial needs and stroke prevention)
4 are not adequately addressed. Self-management programmes exist but the optimal content
5 and delivery approach is unclear.

6 We aim to describe the process undertaken to develop a structured self-management
7 programme to address these unmet needs.

8 ***Materials and Methods***

9 Based on the Medical Research Council framework for complex interventions, the
10 development involved three phases:

11 ‘Exploring the idea’: Evidence synthesis and patient and public involvement (PPI) with
12 stroke survivors, carers and healthcare professionals.

13 ‘The iterative phase’: Development and iterative refinement of the format, content,
14 underpinning theories and philosophy of the self-management programme *My Life After*
15 *Stroke (MLAS)*, with PPI. MLAS consists of two individual appointments and four group
16 sessions over nine weeks, delivered interactively by two trained facilitators. It aims to build
17 independence, confidence and hope and focusses on stroke prevention, maximising physical
18 potential, social support and managing emotional responses. MLAS is grounded in the
19 narrative approach and social learning theory.

20 ‘Ready for research’: The refinement of a facilitator curriculum and participant resources to
21 support programme delivery.

22 ***Results***

1 Through a systematic process, we developed an evidence- and theory-based self-management
2 programme for stroke survivors

3 ***Conclusions***

4 MLAS warrants evaluation in a feasibility study.

5 **Key Words:**

6 Stroke; cerebral vascular accident (CVA); Self-management; intervention;

7

1

2 **Introduction**

3 The longer term problems experienced by people with stroke and their carers are well
4 recognised[1,2]. A UK survey found that stroke survivors wanted more information about
5 stroke and support for the emotional and social impact of stroke, as well as highlighting the
6 many physical and cognitive challenges people face post-stroke (such as memory,
7 concentration problems, and fatigue)[1]. Psychosocial consequences following stroke can
8 have a significant impact on quality of life and long-term functioning[3,4] and there is now a
9 greater recognition and drive to improve people's mental health and well-being[5,6].

10 Providing further information and strategies for stroke prevention are also crucial, as over a
11 quarter of stroke survivors are likely to have another stroke within 5 years and up to 40% at
12 10 years[7].

13 Many stroke services are tailored to stroke survivor needs during the acute period, with long-
14 term support currently consisting of a recommended 6 month follow up and subsequent
15 annual reviews within primary care[8]. While these reviews are recommended and patients
16 should be able to be referred back into appropriate services (such as physiotherapy or
17 psychology) as needs arise [9], there is a disparity in terms of provision and stroke survivors
18 and carers feel abandoned [10]. Furthermore, psychosocial needs increase over time,
19 compared to functional needs which decrease over time, highlighting an additional need for
20 the provision of appropriate services over a longer period of time [11].

21 Self-management programmes (SMPs) in other long-term conditions have demonstrated
22 benefits both in trials as well as implementation[12,13]. Within stroke, the content and
23 format of self-management programmes varies widely[14-16]. There is evidence to support
24 many self-management strategies, especially in relation to behaviour change, self-efficacy

1 and goal-setting[15,17] , but there are no agreed criteria for what a self-management
2 programme should include within stroke. In diabetes, for example, the National Institute for
3 Health and Care Excellence (NICE) guidance advises self-management programmes are
4 tailored to the needs of the individual. Diabetes SMPs are developed with a specific aim to
5 support the person to self-manage their condition. These SMPs are often accompanied by a
6 structured curriculum that is theory-driven and evidence-based, are delivered by trained
7 facilitators and are quality assured and audited regularly[18]. While diabetes and stroke are
8 different diseases, both are long-term conditions which require self-management. With this in
9 mind, our aim was to:

10 Develop an evidence-based, theory-driven, structured self-management programme
11 for stroke survivors to address their unmet psychosocial and information needs about stroke
12 and stroke management.

13

14 **Methods and Findings**

15 The development of the My Life After Stroke (MLAS) programme followed a systematic,
16 iterative process, based on the Medical Research Council framework[19,20] for the
17 development of complex interventions and our in-house pathway and experience for
18 developing SMPs[21-23]. Key aspects of this process are detailed within the phases detailed
19 below and summarised in Figure 1. The core development team included psychologists,
20 nurses and a physiotherapist, alongside a research team. In addition to the expertise in their
21 area, our development team had previous experience in developing and delivering self-
22 management programmes in other long-term conditions [20,24,25] and were well-placed to
23 develop, review, progress and refine this intervention through the process detailed below.

1

2 ***Phase 1 ‘Exploring the idea’***

3 *Literature search*

4 In this phase, a comprehensive literature search was undertaken to identify research of self-
5 management interventions for stroke survivors in order to pragmatically inform the
6 development of our intervention. It was also carried out to check if there was an existing
7 effective intervention that could be used or adapted in order to meet stroke survivors’ needs.

8 The search included studies from 2005-2015 and was limited to pilot studies, randomised
9 controlled trials (RCTs) and systematic reviews of RCTs, in English (see appendix 1 for
10 search terms used). These studies were considered in terms of their sample, details of
11 intervention, primary outcomes and theoretical underpinning, where relevant.

12 The literature review identified 25 RCTs and 6 systematic reviews relevant to the aims of this
13 study. Interventions were delivered individually face-to-face (n=11), group-based (n=7), via
14 telephone (n=3), online (n=2) or as a workbook (n=2). Not all interventions recorded a
15 theoretical underpinning, however, theories that were cited included self-efficacy (n=5),
16 implementation of intentions (n=2), stress and coping (n=2), adult learning theory (n=2) and
17 chronic disease self-management (n=2). Topics across the identified interventions included:
18 understanding stroke (recovery, re-occurrence, medication, prevention), practical advice,
19 managing emotions and behaviours, health behaviour change (promotion of health lifestyle),
20 dealing with stress and fatigue and future focus. Resources used within the interventions
21 included personalised manual/workbook, written tip sheets, card tasks (to identify goals),
22 prevention package, risk factor profiles, keeping well plan, fatigue diary and problem rating
23 sheets. Outcome measures used in studies included measuring quality of life, mental health
24 status, knowledge, self-efficacy and fatigue. Some used general health measures and others,

1 stroke-specific ones. As illustrated in Table 1, a number of important considerations emerged
2 from the literature, which informed our SMP.

3

4 The findings from the literature search were discussed by the development team. In addition
5 to the theories generated in the search, further theories [32,33] were identified as relevant
6 through experience within the core development team. The patient-centred empowerment
7 model[34,35] was also highlighted based on the research team's previous work [36]. Stroke
8 survivors live with the effects of their stroke every minute of every day, yet only access
9 healthcare providers for a limited period of time, therefore empowering patients to make
10 decisions about what is important for them, their health and their life is important to support
11 self-management.

12 *Patient and public involvement (PPI)*

13 Consultation workshops (n=2) were held with stroke healthcare professionals (HCPs) and
14 stroke survivor groups (n=3) separately, to identify each group's perspective on stroke
15 survivor needs, the timing and format of a stroke SMP as well as priorities for content. Each
16 workshop lasted approximately an hour, followed a topic guide (examples provided in
17 appendix 2) and was run by 2 members of the research team; one took the lead for asking
18 questions and facilitating the discussion and the other made notes and asked clarifying
19 questions where necessary. HCPs included 2 physiotherapists, 2 nurses, 1 occupational
20 therapist, 1 speech and language therapist, 1 support worker and 2 consultants. Three
21 separate stroke survivor groups of between 4-8 people (including carers) were consulted
22 across Leicester and Cambridge across the duration of the development process. Members of
23 the research team also had informal discussions with the regional Stroke Association

1 manager, Stroke Association group leader and the Early Supported Discharge Stroke
2 manager.

3 Once a PPI event had taken place, a de-brief immediately occurred between those running the
4 event; their initial thoughts were documented and important themes were highlighted. These
5 were then fed back and discussed with the wider research development team and triangulated
6 alongside evidence from the literature search to iteratively inform and make decisions in
7 relation to the development of our intervention. Topic guides were amended for subsequent
8 consultation workshops, to further discuss, refine or clarify issues.

9 Consultation with stroke HCPs highlighted priority areas for the SMP. One priority included
10 emotional needs and practical strategies to manage low mood. Furthermore, HCPs thought
11 facilitators who would be delivering the SMP would need support and training in this. A
12 second priority included prevention strategies of further strokes, which HCPs believed would
13 be most beneficial if offered after the initial six weeks post-stroke. The rationale for this was
14 that stroke survivors would be better able to process this information once the therapy-intense
15 period had occurred. A third priority was to provide ongoing support and education to aid
16 stroke survivors' recovery, adjustment and adaptation. Again, this would optimally be offered
17 after the acute phase as stroke survivors can feel abandoned as intensive therapy reduces,
18 therefore follow-on support is needed to help this transition. Fourthly, an introductory
19 individual appointment prior to attending group sessions was suggested to help prepare
20 individuals for the SMP, as well as enhancing uptake to the programme. HCPs advised there
21 should be opportunities for stroke survivors to consolidate their understanding throughout the
22 SMP as well as facilitators using simple language and short sentences, to accommodate for
23 memory and other cognitive changes people can have following stroke. It was
24 acknowledged that challenges may exist in offering a SMP suitable for all stroke survivors

1 who are at different stages with varying disabilities and effects (e.g. catering for physical
2 disabilities as well as cognitive and speech problems).

3 Our PPI work with stroke survivors and carers also recommended an individual appointment
4 at the start of the SMP. They stressed the importance of the programme to be held in an
5 accessible, community venue and to include a focus on emotional management and building
6 confidence. Stroke survivors supported the suggestion of the programme consisting of 4-5
7 group sessions and while the duration of each session was not a concern to them, they did
8 prefer sessions to be in the morning, due to the risk of fatigue experienced later in the day.

9 PPI members liked the idea of the narrative approach, journey metaphor and the identified
10 core areas for content (see Figure 2 below), although disagreements about including the topic
11 ‘what is a stroke’ were aired, due to PPI members’ differing personal understanding of stroke.

12 The philosophy of our SMP was developed further through exercises within PPI groups,
13 using hypothesised scenarios of stroke survivors (theories and philosophy are described in
14 detail in phase 2). In addition to providing feedback on the content of the SMP, stroke
15 survivor and carer PPI members decided the name of our SMP: ‘My Life After Stroke’
16 (MLAS). From this point onwards, we will refer to our SMP as MLAS.

17 ***Phase 2 ‘The iterative phase’***

18 *Prototype*

19 Based upon the work from Phase 1, a prototype SMP was developed.

20 *Philosophy*

21 The philosophy underpinning MLAS is patient-centred and one of empowerment. More
22 specifically, *people who have had a stroke seek to maximise their well-being and quality of*
23 *life* which is achieved across four areas: social well-being and integration; acquiring a level of

1 understanding of, and capacity to manage, their emotional responses to living with a stroke;
2 maximise own physical potential (including cognitive and sensory abilities); minimising risk
3 of future stroke.

4 *Theories*

5 The theoretical basis to MLAS was grounded within a narrative approach due to the focus on
6 social and psychological elements of living post-stroke and to accommodate a potential broad
7 range of time since first stroke. This would allow participants to discuss what life was like
8 before and after stroke and become more aware of their journey with stroke[32,33].

9 Another important theory was Social Learning Theory and a main construct of this is self-
10 efficacy. Self-efficacy[37] is key to supporting behaviour change, confidence, independence
11 and overcoming barriers. The format and content of MLAS provide the opportunity for
12 people to share mastery experiences and vicariously learn from, support and motivate, each
13 other. A cognitive behavioural therapy approach was also employed to help people consider
14 how their thoughts, emotions, physiological responses and behaviour interlink, with the aim
15 of participants considering barriers (and subsequently solutions) to achieving physical, social
16 and psychological well-being. In relation to stroke prevention, the capability, opportunity,
17 motivation and behaviour (COM-B) model was consulted to inform and identify techniques
18 to support relevant behaviour change[38,39]. Furthermore, activities within MLAS allows
19 participants to set goals, action plan, problem solve and self-monitor[40], with the support of
20 facilitators. A detailed breakdown of how these theories underpinned the MLAS sessions are
21 shown in Table 2.

22 *Prototype*

23

24 *Aim:* From the work detailed above, the aims of MLAS were to help participants to:

- 1 • Achieve - assist participants to acknowledge and adjust to the new realities of their
2 situation, (including emotional responses) and set themselves new and realistic
3 challenges (including reducing their risk of further stroke)
- 4 • Build hope, independence and confidence - increase their confidence in their abilities
5 and skills to take on new challenges, encourage participants to feel hopeful that they
6 can achieve the aims they set themselves and build independence to live their life.

7

8 In order to support stroke survivors to achieve these aims, content was included across four
9 core topic areas: prevention, psychological, physical and social needs. Through group
10 sessions, facilitation and interactivity, the provision and sharing of information underpins this
11 content. As such, an overall conceptual map was developed (figure 2).

12

13 *Facilitator behaviours:* In order to achieve the aims of MLAS using the identified philosophy
14 and theories, the facilitator's role **while delivering our SMP** was to:

- 15 • Demonstrate a curious, non-judgemental approach towards participants
- 16 • Skilfully support participants to explore their personal thoughts and feelings
- 17 • Avoid giving specific advice and instead support participants to develop their own
18 solutions and strategies to the problems they face
- 19 • Facilitate the group's awareness of sources of support and information
- 20 • Promote the sharing of knowledge and ideas between the participants and signpost
21 where appropriate

22

23 *Format and content:* Through the above work, the SMP format and topics were established.
24 The MLAS programme consists of one 30-45 minute one-to-one individual appointment, 4
25 weekly group sessions of 2.5 hours each and a final 30 minute one-to-one individual

1 appointment 4 weeks after the final group session (see figure 3). Table 2 describes the content
2 across all sessions as well as highlighting the corresponding theory, approach or supportive
3 tool. Carers were also invited to attend if the stroke survivor wished.

4

5 *Draft curriculum and resources:* A curriculum detailing session plans and associated
6 supportive resources were drafted, to support facilitator delivery. Handouts were also created
7 and provided for participants which included an action plan, worksheets to use within
8 sessions and information regarding how to reduce risk for further strokes. Participants could
9 then also refer back to these handouts after sessions, to help them achieve their goals.

10 *Test & Refine*

11 MLAS was tested in two iterative cycles; iteration one enlisted volunteers (10 stroke
12 survivors and 4 carers) from an existing stroke support group in the community and iteration
13 two was delivered to six stroke survivors and three carers who volunteered from contacts
14 within the research development team or wider support groups. Participants remained within
15 the same cohort, to encourage building relationships and support.

16 Two members of the development team (both HCPs with previous experience of SMP
17 delivery) facilitated each session of the programme (with the same two facilitators for each
18 cohort where possible), with an observer making notes. After each iterative session, feedback
19 was obtained from the group about what they felt went well, what didn't go so well, what
20 they would want to change and what they thought about the resources used. Observation
21 notes were discussed within the development team and further amendments made to the draft
22 curriculum plans where necessary. A feedback PPI group was held by a researcher not
23 involved in the delivery at the end of each iteration programme, for participants to share their

1 thoughts and insights on the programme and facilitators. The number of iterations and
2 refinements were balanced between funding availability, feedback and consensus within the
3 research development team.

4 *Feedback*

5 MLAS was well received, with minor amendments made to the content, resources and
6 delivery. Some written activities were changed to a verbal format to accommodate
7 communication needs and physical abilities of participants. Some resources were revised to
8 use less technical language. There was a need to write key summary points, to aid those with
9 memory problems. The narrative journey metaphor was further incorporated and referred to
10 more often throughout MLAS to enhance participant engagement.

11 Feedback led to changes to the ordering and content of some sessions. For example, group
12 sessions 2 and 3 were made interchangeable based on participants' preference and an
13 additional section about relationships was introduced to group session 4 (Figure 4).

14

15 The initial individual appointment was perceived to be fundamental to an effective delivery
16 of MLAS group sessions. This individual appointment allowed stroke survivors the time and
17 freedom to detail their stroke (and often share their frustration of having had a stroke), and
18 reflect on their experience before being able to embrace the MLAS programme. Therefore the
19 first individual appointment was made compulsory (either face-to-face or via telephone) prior
20 to attending the group sessions.

21

22 *Phase 3 'Ready for Research'*

1 Feedback from the iterative phase led to an amended version of MLAS, in which the
2 resulting resources and curriculum were developed. An overview of the final timetable for
3 MLAS can be seen in figure 4. A curriculum detailing key outcomes, content, facilitator
4 behaviours, participant activities and resources to be used for each session, along with a
5 session outline, example open questions and guidance was finalised. Resources, including a
6 road map, action plan and photographic images of ways to manage health and well-being,
7 were produced. Handbooks for participants for each group session were developed, utilising
8 guidance[41] to facilitate reading and understanding, which would be provided in the
9 corresponding group session. This re-iterated information and also provided worksheets and
10 opportunities for participants to write down useful information for themselves. A stroke
11 directory of useful local and national services, groups and support available was also
12 completed. This version would then be tested in a feasibility study with stroke survivors
13 recruited from primary care (details reported elsewhere). Now we had finalised the content,
14 structure and theoretical underpinning of MLAS, the research development team looked
15 more closely at potential outcomes measures we could use as part of the upcoming feasibility
16 study. From the outcome measures identified as part of the literature search and wider
17 investigation, we identified Stroke Self-Efficacy Questionnaire[42], Stroke-Specific Quality
18 Of Life Scale (SS-QOL)[43], Stroke Impact Scale (SIS)[44] and Southampton Stroke Self-
19 Management Questionnaire (SSSMQ)[45] as outcomes relevant to stroke survivors which
20 the intervention might influence.

21

22 *Discussion*

23 This paper has described the systematic process that took place to develop MLAS, a self-
24 management programme for stroke survivors. MLAS was supported by a comprehensive
25 curriculum for facilitators to deliver MLAS as intended, as well as utilising various resources

1 to help support participants through their journey with stroke. MLAS is underpinned by
2 relevant content from the evidence base, the narrative approach and social learning theories,
3 goal setting and action planning in order to support people to adjust, achieve and build hope,
4 independence and confidence following stroke. The development of MLAS utilised stroke
5 survivor input and feedback throughout.

6 A variety of self-management interventions for stroke survivors have been developed, which
7 include face-to-face and telephone delivery, in individual and group formats. Collectively,
8 they provide low-quality evidence that participants experience improvement in quality of life
9 and self-efficacy[16]. Characteristics of MLAS that differentiate it from previous
10 programmes are its target population (longer-term stroke survivors and their carers, recruited
11 from primary care) and being applicable for a UK health service. To our knowledge, MLAS
12 is the only intervention that explicitly details the underpinning theories and philosophy of the
13 programme and utilises a written curriculum, trained facilitators and a quality assurance
14 process, which draws upon experience and guidelines in other long-term conditions[12,18] .

15 During the first group session of the first iterative programme, participants focused on the
16 emotional management aspects of stroke whereas during the second iteration, participants'
17 focus was towards stroke prevention. This may simply reflect the different needs of different
18 participants. Alternatively, for the first iteration, participants were recruited from one stroke
19 support group, where they often had guest speakers, so these participants may already have
20 felt knowledgeable about stroke prevention. However, participants in the second iteration,
21 were recruited from different sources and had not met before, so their experiences and
22 knowledge may have been different (which may more accurately represent real-world where
23 referrals are likely to be from different sources). Therefore, we enabled group sessions
24 'Roadblocks' and 'Managing Health and Well-being' to be interchangeable, so that the needs

1 of the group inform the session order. At the end of the ‘Stroke Journey’, a consensus
2 decision is made by the group, regarding which session is delivered next.

3 Input from healthcare professionals, stroke survivors and carers was vital within the
4 development of MLAS, as guidelines recommend [20]. Further feedback was sought from
5 stroke survivors and carers during testing of the first iterative versions of MLAS. This helped
6 to make MLAS as relevant, helpful and appropriate to as many stroke survivors as possible,
7 taking into account the wide range of difficulties and disabilities stroke can cause.

8 It is appreciated that it may be difficult for stroke survivors to attend all six sessions due to
9 other conflicting appointments or commitments. However, the individual appointment
10 (preferably delivered face-to-face but could be achieved via telephone) and group session one
11 were deemed mandatory for participants. This is because of the importance of allowing
12 participants to share details of their stroke privately, for the facilitator to understand any
13 adaptations the participant may need for the group sessions and for participants to understand
14 the narrative approach and the journey metaphor, which is referred to throughout all MLAS
15 sessions. It appeared extremely valuable for participants to detail their stroke during their
16 individual appointment in order to allow them to move on. This may be because it was the
17 first opportunity they had had to discuss this significant event; GP appointments tend to be a
18 short and problem-focussed and therapy input tends to focus on a physical problem and goal.
19 Conversely, MLAS provides an opportunity for participants to be listened to and enables
20 them to reflect and problem-solve with appropriate support. However, for stroke survivors to
21 go into great detail and description of their stroke can be disruptive and time-consuming
22 within the group sessions, hence the importance of the first individual appointment.

23 A potential limitation of this work was that funding and time allowance meant we only
24 carried out two iterations in order to refine MLAS. However, given the amount of PPI in

1 developing MLAS, the positive feedback gained during the iterations and the limited
2 modifications that were needed between the two iterations, this was probably adequate prior
3 to a feasibility study. Most participants were White British so MLAS may need further
4 adaptation for Black and Minority Ethnic stroke survivors. As the feasibility of MLAS is yet
5 to be tested, additional costs for translation and cultural adaptation had not yet been
6 considered. Given the patient-centred nature of MLAS, with patient's sharing their own
7 narrative and accessible information guidelines [41] being followed, hopefully much of
8 MLAS is translatable across different ethnicities and cultures. However further work,
9 utilising culturally-relevant PPI may be needed after further evaluation of MLAS.

10 In conclusion, we have developed an evidence-based, theory-driven self-management
11 programme for stroke survivors with the aim of addressing feelings of abandonment and
12 providing self-management support later in their stroke journey. Feedback from MLAS was
13 positive, with minimal amendments implemented. Further comprehensive evaluation is
14 necessary to determine its acceptability and effectiveness; MLAS has subsequently been used
15 as part of a feasibility and cluster randomised controlled trial within primary care[46].

16 **Acknowledgements**

17 The MLAS development group involved a number of team members including Rosie Horne,
18 Clare Makepeace, Lorraine Martin Stacey, Yvonne Doherty, Jayna Mistry as well as
19 facilitators and PPI members who contributed to various aspects of study set up, trial
20 management, intervention development, refinement and delivery for who we are thankful to.

21 **Conflicts of Interest:**

22 The University of Cambridge, University of Leicester and University Hospitals of Leicester
23 NHS Trust received funding from the National Institute for Health Research (NIHR)

1 [Programme Grants for Applied Research (PTC-RP-PG-0213-20001)] to carry out this work.
2 The views expressed are those of the authors and not necessarily those of the NIHR or the
3 Department of Health and Social Care.
4 VJ, LA, MC, EK, RM, JM, MJD are, or were, employed through their respective
5 organisations during this work. Intellectual property rights are held through the University of
6 Leicester on behalf of the DESMOND collaborative at Leicester Diabetes Centre.

7

8

9 *References*

10

- 11 1. McKeivitt C, Fudge N, Redfern J, et al. Self-reported long-term needs after stroke. *Stroke*.
12 2011;42(5):1398-1403.
- 13 2. Department of Health . Cardiovascular Disease Outcomes Strategy: Improving outcomes for
14 people with or at risk of cardiovascular disease. 2013.
- 15 3. Kirkeveld M, Bronken BA, Martinsen R, et al. Promoting psychosocial well-being following a
16 stroke: developing a theoretically and empirically sound complex intervention. *International*
17 *journal of nursing studies*. 2012;49(4):386-397.
- 18 4. Kirkeveld M, Martinsen R, Bronken BA, et al. Promoting psychosocial wellbeing following
19 stroke using narratives and guided self-determination: a feasibility study. *BMC Psychology*.
20 2014;2(1):4.
- 21 5. Department of Health. No health without mental health. 2011.
- 22 6. NHS Improvement. Psychological care after stroke: Improving stroke services for people with
23 cognitive and mood disorders. 2011.
- 24 7. Mohan KM, Wolfe CD, Rudd AG, et al. Risk and cumulative risk of stroke recurrence: a
25 systematic review and meta-analysis. *Stroke*. 2011;42(5):1489-1494.
- 26 8. NICE. Stroke in adults; quality standard. 2010.
- 27 9. Stroke Association. State of the nation: Stroke statistics. . 2018.
- 28 10. Pindus DM, Mullis R, Lim L, et al. Stroke survivors' and informal caregivers' experiences of
29 primary care and community healthcare services - A systematic review and meta-
30 ethnography. *PLoS One*. 2018;13(2):e0192533.
- 31 11. Taylor SJC, Pinnock H, Epiphaniou E, et al. Health Services and Delivery Research. A rapid
32 synthesis of the evidence on interventions supporting self-management for people with
33 long-term conditions: PRISMS - Practical systematic Review of Self-Management Support for
34 long-term conditions. Southampton (UK): NIHR Journals Library 2014.
- 35 12. Davies MJ, Heller S, Skinner TC, et al. Effectiveness of the diabetes education and self
36 management for ongoing and newly diagnosed (DESMOND) programme for people with

- 1 newly diagnosed type 2 diabetes: cluster randomised controlled trial. *BMJ*.
2 2008;336(7642):491.
- 3 13. Skinner TC, Carey ME, Cradock S, et al. Diabetes Education and Self-Management for
4 Ongoing and Newly Diagnosed (DESMOND): process modelling of pilot study. *Patient*
5 *education and counseling*. 2006 Dec;64(1-3):369-77.
- 6 14. Lennon S, McKenna S, Jones F. Self-management programmes for people post stroke: a
7 systematic review. *Clinical rehabilitation*. 2013 Oct;27(10):867-78.
- 8 15. Warner G, Packer T, Villeneuve M, et al. A systematic review of the effectiveness of stroke
9 self-management programs for improving function and participation outcomes: self-
10 management programs for stroke survivors. *Disability and rehabilitation*. 2015;37(23):2141-
11 63.
- 12 16. Fryer CE, Luker JA, McDonnell MN, et al. Self management programmes for quality of life in
13 people with stroke. *Cochrane Database of Systematic Reviews*. 2016 (8).
- 14 17. de Silva D. Evidence: Helping people to help themselves. London: The Health Foundation;
15 2011.
- 16 18. NICE. Type 2 diabetes in adults: management (NG28). 2015.
- 17 19. Craig P, Dieppe P, Macintyre S, et al. Developing and evaluating complex interventions: the
18 new Medical Research Council guidance. *BMJ*. 2008;337:a1655.
- 19 20. Campbell M, Fitzpatrick R, Haines A, et al. Framework for design and evaluation of complex
20 interventions to improve health. *BMJ*. 2000;321(7262):694.
- 21 21. Troughton J, Chatterjee S, Hill SE, et al. Development of a lifestyle intervention using the
22 MRC framework for diabetes prevention in people with impaired glucose regulation. *J Public*
23 *Health (Oxf)*. 2016 Sep;38(3):493-501.
- 24 22. Stone M, Patel N, Daly H, et al. Using qualitative research methods to inform the
25 development of a modified version of a patient education module for non-English speakers
26 with type 2 diabetes: experience from an action research project in two South Asian
27 populations in the UK. *Diversity in Health and Social Care*. 2008 09/01;5:199-206.
- 28 23. Carey M, Daly H. Developing and piloting a structured, stepped approach to patient
29 education. *Prof Nurse*. 2004 Oct;20(2):37-9.
- 30 24. Smith J, Forster A, Young J. A randomized trial to evaluate an education programme for
31 patients and carers after stroke. *Clinical rehabilitation*. 2004 2004/11/01;18(7):726-736.
- 32 25. Apps LD, Mitchell KE, Harrison SL, et al. The development and pilot testing of the self-
33 management programme of activity, coping and education for chronic obstructive
34 pulmonary disease (SPACE for COPD). *Int J Chron Obstruct Pulmon Dis*. 2013;8:317-327.
- 35 26. Cheng HY, Chair SY, Chau JP. The effectiveness of psychosocial interventions for stroke
36 family caregivers and stroke survivors: a systematic review and meta-analysis. *Patient*
37 *education and counseling*. 2014 Apr;95(1):30-44.
- 38 27. Pfeiffer K, Beische D, Hautzinger M, et al. Telephone-based problem-solving intervention for
39 family caregivers of stroke survivors: a randomized controlled trial. *Journal of consulting and*
40 *clinical psychology*. 2014 Aug;82(4):628-43.
- 41 28. Marsden D, Quinn R, Pond N, et al. A multidisciplinary group programme in rural settings for
42 community-dwelling chronic stroke survivors and their carers: a pilot randomized controlled
43 trial. *Clinical rehabilitation*. 2010 Apr;24(4):328-41.
- 44 29. Sabariego C, Barrera AE, Neubert S, et al. Evaluation of an ICF-based patient education
45 programme for stroke patients: A randomized, single-blinded, controlled, multicentre trial of
46 the effects on self-efficacy, life satisfaction and functioning. *British Journal of Health*
47 *Psychology*. 2013;18(4):707-728.
- 48 30. Cadilhac DA, Hoffmann S, Kilkenny M, et al. A phase II multicentered, single-blind,
49 randomized, controlled trial of the stroke self-management program. *Stroke*. 2011
50 Jun;42(6):1673-9.

- 1 31. Jones F, Mandy A, Partridge C. Changing self-efficacy in individuals following a first time
2 stroke: preliminary study of a novel self-management intervention. *Clinical rehabilitation*.
3 2009 Jun;23(6):522-33.
- 4 32. Chow EO. Narrative therapy an evaluated intervention to improve stroke survivors' social
5 and emotional adaptation. *Clinical rehabilitation*. 2015 Apr;29(4):315-26.
- 6 33. Chow EO. Responding to Lives after Stroke: Stroke Survivors and Caregivers Going on
7 Narrative Journeys *The International Journal of Narrative Therapy and Community Work*
8 2013 1 July 2013;4.
- 9 34. Anderson RM, Funnell MM. Patient empowerment: myths and misconceptions. *Patient*
10 *education and counseling*. 2010;79(3):277-282.
- 11 35. Funnell MM, Anderson RM. Empowerment and Self-Management of Diabetes. *Clinical*
12 *Diabetes*. 2004;22(3):123.
- 13 36. Davies MJ, Heller S, Skinner T, et al. Effectiveness of the diabetes education and self
14 management for ongoing and newly diagnosed (DESMOND) programme for people with
15 newly diagnosed type 2 diabetes: cluster randomised controlled trial. *Bmj*.
16 2008;336(7642):491-495.
- 17 37. Bandura A. Self-efficacy: toward a unifying theory of behavioral change. *Psychological*
18 *review*. 1977 Mar;84(2):191-215.
- 19 38. Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for
20 characterising and designing behaviour change interventions. *Implementation science : IS*.
21 2011 Apr 23;6:42.
- 22 39. Michie S, Richardson M, Johnston M, et al. The Behavior Change Technique Taxonomy (v1)
23 of 93 Hierarchically Clustered Techniques: Building an International Consensus for the
24 Reporting of Behavior Change Interventions. *Annals of Behavioral Medicine*. 2013;46(1):81-
25 95.
- 26 40. NICE. Behaviour change: individual approaches (PH49). 2014.
- 27 41. Stroke Association. Accessible Information Guidelines. London: Stroke Association; 2012.
- 28 42. Jones F, Partridge C, Reid F. The Stroke Self-Efficacy Questionnaire: measuring individual
29 confidence in functional performance after stroke. *Journal of clinical nursing*. 2008
30 Apr;17(7b):244-52.
- 31 43. Williams LS, Weinberger M, Harris LE, et al. Development of a Stroke-Specific Quality of Life
32 Scale. *Stroke*. 1999;30(7):1362-1369.
- 33 44. Duncan PW, Bode RK, Min Lai S, et al. Rasch analysis of a new stroke-specific outcome scale:
34 the stroke impact scale11No commercial party having a direct financial interest in the results
35 of the research supporting this article has or will confer a benefit upon the author(s) or upon
36 any organization with which the author(s) is/are associated. *Archives of Physical Medicine*
37 *and Rehabilitation*. 2003 2003/07/01/;84(7):950-963.
- 38 45. Boger EJ, Hankins M, Demain SH, et al. Development and psychometric evaluation of a new
39 patient -reported outcome measure for stroke self -management: The Southampton Stroke
40 Self - Management Questionnaire (SSSMQ). *Health Qual Life Outcomes*. 2015;13:165-165.
- 41 46. Mullis R, Aquino MRJ, Dawson SN, et al. Improving Primary Care After Stroke (IPCAS) trial:
42 protocol of a randomised controlled trial to evaluate a novel model of care for stroke
43 survivors living in the community. *BMJ Open*. 2019;9(8):e030285.

44

45

1 Tables

Table 1: Findings from the literature and how this was used to inform our self-management programme	
Finding	How this was used to inform our programme
<ul style="list-style-type: none"> • The optimal dose and timing of interventions post-stroke is yet to be determined[26] • Information and support given immediately post-stroke is often not accessed or retained[24] • Psychological and social needs increase over time, compared to physical needs that tend to reduce following the immediate rehabilitation phase[11]. 	<ul style="list-style-type: none"> • Stroke survivors are encouraged to attend at any point from diagnosis (no upper limit) except during the immediate rehabilitation phase, where functional needs are most prominent • Narrative approach and journey metaphor is used for stroke survivors to tell their story, irrespective of how long ago their stroke was • Opportunities for stroke survivors to share ideas and support are included • A stroke directory is provided to inform stroke survivors of local and national organisation or groups that may help • Problem solving and cognitive behaviour therapy approaches are used. • Participant handbooks are provided weekly to back up information provided and skills learnt

<ul style="list-style-type: none"> • Carers have emotional needs [27,28] 	<ul style="list-style-type: none"> • Carers are invited to attend with stroke survivor • Opportunities for separate carer and stroke survivors activities and discussions are provided, to allow open, honest conversations and different perspectives to be explored
<ul style="list-style-type: none"> • A one to one face-to-face contact at the start of the intervention is important[27] 	<ul style="list-style-type: none"> • The format of the intervention includes an individual appointment at the start of the intervention
<ul style="list-style-type: none"> • A community venue may help facilitate integration and attendance[28] 	<ul style="list-style-type: none"> • It is recommended that the intervention is delivered in an easily accessible community setting
<ul style="list-style-type: none"> • A standardised format helps to focus and structure[29] the content and allows information to be shared and reinforced at subsequent sessions (i.e. weekly)[30]. 	<ul style="list-style-type: none"> • Each group session begins with a recap of the previous week’s topic, introduction to this week’s session and ends with a ‘what will I do now’ section. • The intervention is spread over several weeks to allow opportunities for reflection and review
<ul style="list-style-type: none"> • Content should be individualised and determined by personal goals, rather 	<ul style="list-style-type: none"> • Stroke survivors are encouraged to make a personally relevant action plan

<p>than being professionally directed and there should be a focus on self-efficacy enhancing strategies[26,27,29,31].</p>	<ul style="list-style-type: none"> Facilitators encourage discussions between stroke survivors, rather than being didactic
---	---

1

2

3 Table 2: Topics and corresponding theories and strategies to support the programme aims

4 within each session of MLAS

Session	Topics	Corresponding theory, model or approach to support programme aims	Tools used within the session to support
Individual appointment (pre-group session)	<ul style="list-style-type: none"> Outline of MLAS programme and group session commitments. Opportunity for participant to share their personal stroke experience and story. Identification of potential barriers to attendance or participation and 	<ul style="list-style-type: none"> Narrative approach. COM-B: Opportunity 	<ul style="list-style-type: none"> Individual record sheet: record key components of their story of living with stroke and anything that can be done to support participants to

	supportive strategies to address		attend group sessions
Group Session: Stroke journey	<ul style="list-style-type: none"> • Introduce MLAS programme and the narrative approach and supporting road map resource. • Education: what is a stroke (and neuroplasticity)? • Emotional reactions to stroke from stroke survivor and carer perspective (the stroke passenger analogy). • Opportunity to set a goal/action for the next week. 	<ul style="list-style-type: none"> • Narrative approach • COM-B: Psychological capability 	<ul style="list-style-type: none"> • Map resource and metaphor of a car journey used to discuss experiences post-stroke.
Group Session: Managing health & wellbeing	<ul style="list-style-type: none"> • Review of previous weeks actions/goals • Education: Risk factors for stroke and & lifestyle changes to reduce stroke risk. 	<ul style="list-style-type: none"> • COM-B: Psychological capability; Reflective & automatic 	<ul style="list-style-type: none"> • Motivational interviewing: Decisional balance.

	<ul style="list-style-type: none"> • Making lifestyle changes: emotions and motivation. • Action plan. 	<ul style="list-style-type: none"> motivation; Social opportunity • Social learning theory 	<ul style="list-style-type: none"> • SMART goal setting and action planning
<p>Group Session:</p> <p>Roadblocks</p>	<ul style="list-style-type: none"> • Review of previous weeks actions/goals • Roadblocks on the journey: barriers and circumstances that block managing life after stroke. • Problem solving. • Opportunity to set goal/action for next week. 	<ul style="list-style-type: none"> • Cognitive behavioural therapy approach • Problem solving therapy approach 	<ul style="list-style-type: none"> • Roadblocks on the map resource (journey metaphor)
<p>Group Session:</p> <p>Moving forwards on my journey</p>	<ul style="list-style-type: none"> • Review of previous weeks actions/goals. • Your relationships* • Revisit stroke journey and recap main messages of programme. 	<ul style="list-style-type: none"> • Problem-solving therapy approach • COM-B: Reflective motivation; Physical opportunity 	<ul style="list-style-type: none"> • Map resource (journey metaphor) • ‘What will I do now?’ worksheet

	<ul style="list-style-type: none"> • Moving forward – how will health and wellbeing be maintained post programme. • Opportunity to set goal/action. 		
Final individual appointment	<ul style="list-style-type: none"> • Provide closure to the programme. • Reflection on programme and any further needs. • Signpost to other services. 	<ul style="list-style-type: none"> • Narrative approach. 	<ul style="list-style-type: none"> • Individual copy of map resource • Journey metaphor to reflect on where participants feel they are now
<p>*topic added in following the iterations based on feedback</p> <p>COM-B – The Capability, Opportunity, Motivation –Behaviour model</p>			

1 **Figures**

2 Figure 1: Key steps in the development process of the self-management programme

3 Figure 1 Alt Text: A figure showing that on the left, exploring the idea is the first part of
4 developing a self-management programme, which leads into a cycle of developing a
5 prototype, testing it out and refining it, ending on the right of the figure with a programme
6 that is ready for research.

7

8 Figure 2: The aim and core focus of the MLAS programme

9 Figure 2 Alt Text: An image with a circle in the middle saying achieve, to represent the main
10 aim of MLAS. Surrounding this is another circle saying hope, independence and confidence,
11 which MLAS aims to build or maintain. Surrounding that is a circle saying prevention,
12 physical, social and psychological which are the four main topic areas in MLAS. Surrounding
13 all this is information, as information sharing underpins the topic areas.

14

15 Figure 3: Format of the MLAS programme

16 Figure 3 Alt Text: An image with 6 boxes, the first box on the left shows the first session of
17 MLAS is an individual appointment with a facilitator, lasting 45 minutes. To the right of this,
18 are four subsequent boxes, showing the next sessions of MLAS are group sessions, each one
19 week apart and lasting 2.5 hours titled Stroke Journey, Managing Health and Wellbeing,
20 Road blocks and finally Moving Forward on my Journey. The last box on the right shows the
21 final session is an individual appointment with the facilitator lasting 30 minutes, which is 4
22 weeks after the final group session

23

- 1 Figure 4: Timetable and content of sessions for MLAS following the iterations
- 2 Alt Text Figure 4: A flow chart showing the ordering of sessions after revisions. A participant
- 3 will have a first individual appointment, then attend the Stroke Journey group session then
- 4 will undertake either option A (Managing Health and Wellbeing followed by Roadblocks
- 5 session) or option B (Roadblocks then managing health and wellbeing). Whether option A or
- 6 B is taken, all participants' final group session is Moving Forward on my Journey followed
- 7 by the final individual appointment.
- 8