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Collaborative design of a decision aid for stroke survivors with multimorbidity: a qualitative study in the UK engaging key stakeholders

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7 **Collaborative design of a decision aid for stroke survivors with multimorbidity: a**
8 **qualitative study in the UK engaging key stakeholders**
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ABSTRACT

Objectives: Effective secondary stroke prevention strategies are sub-optimally used. Novel development of interventions to enable healthcare professionals and stroke survivors to manage risk factors for stroke recurrence are required. We sought to engage key stakeholders in the design and evaluation of an intervention informed by a Learning Health System approach, to improve risk factor management and secondary prevention for stroke survivors with multimorbidity.

Design: Qualitative, including focus groups, semi-structured interviews and usability evaluations. Data was audio-recorded, transcribed and coded thematically.

Participants: Stroke survivors, carers, health and social care professionals, commissioners, policy makers and researchers.

Setting: Stroke survivors were recruited from the South London Stroke Register; health and social care professionals through South London general practices and King's College London (KCL) networks; carers, commissioners, policy-makers and researchers through KCL networks.

Results: 53 stakeholders in total participated in focus groups, interviews and usability evaluations. Thirty-seven participated in focus groups and interviews, including stroke survivors and carers (N=11), health and social care professionals (N=16), commissioners and policy-makers (N=6) and researchers (N=4). Sixteen participated in usability evaluations, including stroke survivors (N=8) and general practitioners (GPs; N=8). Eight themes informed the collaborative design of DOTT (Deciding on Treatments Together), a decision aid integrated with the electronic health record system, to be used in primary care during clinical consultations between the healthcare professional and stroke survivor. DOTT aims to facilitate shared decision making on personalised treatments leading to improved treatment adherence and risk control. DOTT was found acceptable and usable among stroke survivors and GPs during a series of evaluations.

Conclusions: Adopting a user-centred data-driven design approach informed an intervention that is acceptable to users and has the potential to improve patient outcomes. A future feasibility study and subsequent clinical trial will provide evidence of the effectiveness of DOTT in reducing risk of stroke recurrence.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- Engaging a range of stakeholders in the design and evaluation of an intervention ensures that the intervention is in line with the needs reported by the different stakeholders (e.g., stroke survivors, healthcare professionals, policy makers).
- Adopting a Learning Health System approach enables the delivery of personalised recommendations in real time whilst simultaneously capturing additional data back into the system, to improve the system's predictive model and recommendations.
- As only stroke survivors able to attend the focus groups participated in the study, we did not elicit the views of stroke survivors who are less mobile or housebound.

INTRODUCTION

Stroke is the second leading cause of death and a major cause of disability worldwide.¹ In 2015, there were 3.7 million people living with stroke as a chronic condition in Europe and this number is expected to reach 4.6 million in 2035.² Stroke survivors have a nearly 40% cumulative risk of recurrence during the first 10 years after stroke.³ Secondary stroke prevention requires healthcare professionals to offer effective interventions to monitor and manage risk factors, and for patients to change health related behaviours (e.g., smoking)⁴ and adhere to preventative medications (e.g., to control hypertension).⁵ Follow-up appointments with clinicians offer opportunities to discuss interventions for reducing the risk of future stroke. However, long-term stroke care is characterised by a lack of continuity⁶ and modifiable risk factors are currently not well detected, managed or controlled post stroke.⁷

Interventions designed to improve risk-factor management among stroke survivors in randomised controlled trials (RCTs) have shown modest or no effect. A recent Cochrane systematic review of 42 RCTs evaluating the effectiveness of educational and behavioural or organisational interventions on modifiable risk factor control for secondary prevention of stroke, found no clear benefit in any of the target outcomes (i.e., blood pressure, lipid profile, HbA1c, BMI and recurrent cardiovascular events).⁸ Possible reasons could be that these interventions have not been part of the clinical decision-making process of clinicians, did not engage various stakeholders in the design of the intervention, and were not integrated with the Electronic Health Record (EHR) (with the exception of one study⁹) - all of which are considered critical features of successful clinical decision support systems.^{10,11}

Stroke survivors commonly experience multimorbidity.¹² Gallacher and colleagues found that 94% of the people with stroke had one or more additional morbidities and often experienced long-term physical, psychological and social consequences.¹² This makes improving long-term stroke care a complex endeavour, requiring patient engagement, high quality up-to-date information and a holistic approach which focuses on the patient and not on the disease.¹³ These aspects are important both to plan effective treatments for individual patients and guide best practice for the stroke population in general.¹⁴

The Learning Health System (LHS) 'focusses on approaches to capture data from clinical encounters and other health-related events, analyse the data to generate new knowledge, and then apply this knowledge to continuously inform and improve health decision making and practice.'^{15(p.177)} In a recent report (2019) stating what the NHS can learn from the LHS, the authors argue that it is necessary to utilise data to transform services, not just to digitise current ways of working.¹⁶ Thus, LHS outputs can provide tailored information on optimal care decisions and be delivered at the point of clinical care.¹⁷

Decision support systems (DSS) which aim to analyse a patient's characteristics to provide tailored recommendations (such as for diagnosis,¹⁸ treatment or long-term management), implement this transfer of evidence into practice. This is done particularly when used in conjunction with sources of 'Real World Data'¹⁹ such as EHR systems that capture detailed data on specific conditions. Such point-of-care DSS support a range of applications, including identifying patient risk estimation, providing guidance on the appropriateness of treatments, and tailoring clinical information to specific patient needs - providing the right care to the right patient at the right time.¹⁷ A few studies have reported that engaging stakeholders to develop a LHS and integrated DSS improved patient outcomes and processes of care for individuals with long-term conditions.^{20,21}

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3 Increasingly patients are expecting to be informed and involved in their care.²² This shift from
4 imposition of professional opinion towards a more collaborative model of care is not only relevant
5 when people face difficult decisions about their health, where there are high stakes and where
6 outcomes are uncertain, but also in situations where people need to manage long term conditions or
7 consider making changes in their lifestyles in order to reduce future risks.²³ Such shared decision
8 making (SDM) respects patient values and preferences, and supports decision-making through the
9 provision of high-quality, accessible information.²⁴ SDM has been found to be most effective if
10 interventions are developed for use during the clinical encounter,²⁵ and several DSS that have been
11 designed to facilitate SDM during the consultation (i.e., decision aids) have shown improved treatment
12 adherence and clinical outcomes in patients with chronic conditions such as asthma and diabetes.^{26,27}

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17 In his seminal analysis, Berg criticised the 'top-down' technology centred approach to designing
18 decision support systems.²⁸ He described an alternative *socio-technical* approach, where new tools
19 needed to be designed taking into account the real-world complex networks of people involved in
20 health care, and designed using an iterative approach which makes strong use of qualitative research
21 with users.

22 23 24 25 **Aims and objectives**

26 The aim of this study was to engage key stakeholders to identify priorities and information needs in
27 long term stroke care and collaboratively design and evaluate a selected intervention that could be
28 integrated as part of the EHR system informed by a LHS approach. The data supporting the selected
29 intervention are based on linked datasets from the South London Stroke Register (SLSR),²⁹ which
30 includes more than 6,000 records of first-ever strokes that occur in South London, and Lambeth
31 Datanet (LDN)³⁰ containing primary care data of local general practices in South London.

32 33 34 35 **METHOD**

36 37 38 **Patient and public involvement**

39 The design was informed by active feedback from stroke survivors and carers from King's College
40 London's Stroke Research Patient and Family Group (SRPFG)³¹, a service user research group which
41 consists of 32 participants currently on the SLSR who are from diverse socio-economic and ethnic
42 backgrounds. Stroke survivors, carers, health and social care professionals, commissioners, policy
43 makers and researchers were involved throughout the study in a collaborative design and evaluation
44 process.

45 46 47 48 **Data collection**

49 We used a range of methods to engage stakeholders (N=53) in the design and evaluation of the
50 intervention, including focus groups, face to face interviews and usability evaluations (see topic guides
51 and interview questions in the supplementary files). The process involved three main stages: (1)
52 exploring stakeholder priorities for data and information needs to inform potential solutions for long-
53 term stroke care; (2) collaborative design of the selected intervention with stakeholders, comprising
54 cycles of design, prototyping and evaluation; (3) Usability and acceptability evaluation of the DSS
55 prototype (See Figure 1). Thirty-seven stakeholders participated in the first two stages, including
56 stroke survivors and carers (N=11), health and social care professionals (N=16), commissioners and
57 policy makers (N=6) and researchers (N=4). Sixteen stakeholders participated in the third stage,
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3 including 8 stroke survivors and 8 General practitioners (GPs). Stroke survivors were recruited from
4 the SLSR. Health and social care professionals were recruited through general practices in South
5 London and King's College London networks. Carers, commissioners, policy makers and researchers
6 were also recruited through these networks. Stakeholders were purposively sampled to include stroke
7 survivors (i.e. men and women, with a range of disabilities and long-term conditions, risk factors and
8 length of time since their stroke) and professionals providing all types of stroke care and support. See
9 Table 1 for details of all stakeholders taking part in the study. Participants could take part in the study
10 if they were able to attend the meetings and were willing to sign a consent form. Transport was
11 arranged for less mobile patients.
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15 <Insert Figure 1 here>
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17 **Stage 1: Exploring stakeholder priorities for data and information needs**

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19 In total, 37 stakeholders participated in this stage. An initial stakeholder engagement meeting
20 comprising 24 participants (SEM), 9 face to face interviews with key stakeholders who could not
21 attend this meeting, and a second focus group involving 12 participants (FG2) were conducted (some
22 participants took part on multiple occasions). The methods and findings from this stage of the study
23 have been reported elsewhere.¹⁴ In brief, in the initial engagement meeting (SEM), participants were
24 introduced to the concept of a LHS and then in three separate focus groups (service user/carer; health
25 and social care professionals; commissioners and policy makers) they were asked to identify priorities
26 and potential solutions that may be derived from the clinical data to improve long-term stroke care
27 for stroke survivors with multimorbidity. Then, in the larger group, through a process of priority setting
28 and consensus led by a facilitator (ES), stakeholders identified a number of priorities and solutions to
29 improve long-term management of stroke (i.e. improving continuity of care; improving management
30 of mental health consequences; better access to health and social care; and targeting multiple risk
31 factors). Targeting multiple risk factors after stroke was identified among stakeholders as a key
32 priority, and a DSS to improve secondary prevention after stroke to target multiple risk factors was
33 subsequently chosen within a smaller core stakeholder group (FG3) for further development. This core
34 stakeholder group (N=12) comprised stroke survivors, healthcare professionals, carer, policy maker
35 and commissioner, and worked collaboratively with the research team to subsequently design the
36 intervention and to provide their active feedback.
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44 **Stage 2: Collaborative design and prototyping of selected intervention**

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46 The initial design of the DSS to improve secondary stroke prevention and target multiple risk factors
47 after stroke was informed by the first stage and guided by the International Patient Decision Aids
48 Standards (IPDAS),²³ which provides a framework and standards for the design of patient decision aids,
49 and the SDM model for clinical practice.³² The latter provides a model of how to conduct shared
50 decision making in practice based on providing patients choice, a range of options and involving them
51 in 'decision talk'. Following feedback from the core stakeholder group at the third focus group meeting
52 above (N=10) (FG3), an updated design of the intervention was subsequently reviewed by the core
53 stakeholder group at a fourth focus group (N=9) (FG4) and was revised following their feedback. The
54 DSS was also presented to the King's College London's SRPFG. The intervention was revised and the
55 updated design was developed as a basic prototype and was further discussed during a subsequent
56 focus group with the core stakeholder group (N=9) (FG5) and the SRPFG. This process allowed all
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stakeholders to iteratively develop and refine the DSS to a working prototype.

Stage 3: Usability and acceptability evaluation of the DSS

Sixteen participants, including eight stroke survivors and eight GPs participated in the usability and acceptability evaluation of the working prototype of the DSS. None had taken part in the previous stages of the study.

The evaluation included simulated consultations using the DSS prototype. In the GPs session, the researcher acted as the patient, and in the stroke patient's session, the researcher acted as the GP. GPs were given a short tutorial on how to use the DSS before the simulated consultations and stroke survivors were given a short explanation about the DSS. GPs and stroke survivors were interviewed after the simulated consultation, asking them to provide feedback on the DSS, including its strengths, limitations and suggestions for improvements. Stroke survivors and GPs also answered an acceptability questionnaire³³ and the System Usability Scale (SUS).³⁴ Acceptability relates to the comprehensibility of the components of the decision aid, including its length, pace, amount of information, balance in presentation and overall suitability.³³ Usability is 'the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use'.³⁵ The SUS is composed of 10 questions and has been shown to be a reliable and psychometrically validated tool.³⁶ Ratings were provided on 5-point Likert scales from 1 (strongly disagree) to 5 (strongly agree), with higher ratings indicating higher satisfaction.

For the usability evaluation, the DSS prototype had the following functionality and flow:

- Stroke survivors (patients) indicated their perceived risk of having a recurrent stroke.
- GPs entered the patient's characteristics (age, gender, clinical conditions).
- The system displayed a 'typical' recurrent stroke risk (age group specific average)³⁷ and the most effective treatments based on the patient's characteristics.
- The benefit of each treatment in terms of reducing the stroke risk was displayed. Estimated relative stroke risk reductions were calculated based on the existing literature.³⁸⁻⁴¹
- Information and common concerns for each treatment were displayed.
- The GP and patient decided on a management plan whilst identifying desired clinical and patient outcomes.
- Patients were told that their management plan would be printed to take home.

Table 1. Stakeholders taking part in the study

Type of stakeholder	SEM (N=24)	Interviews (N=9)	FG2 (N=12)	FG3 (N=10)	FG4 (N=9)	FG5 (N=9)	Usability evaluation (N=16)	Total (N=53*)
Stroke survivor	10		2	2	2	2	8	18
Carer	1		1	1	1	1		1
Health and social care professional	8	7	3	2	2	2	8	22
GP	2	5	1	1	1	1	8	13
Physiotherapist	2		1					2
Speech and language therapist	1							1
Social care professional	1							1
Public health doctor	1							1
Consultant psychiatrist	1							1
Occupational therapist			1	1	1	1		1

Acute stroke care consultant		2					2
Policy makers and commissioners	3	2	2	2	2	2	6
Third sector representatives	2						2
Academic researchers (social scientist, researchers working with SLSR/LDN databases)			4	3	2	2	4

Notes:

1. *Overall 53 participants took part in the study, but a number of stakeholders took part on multiple occasions.
2. King's College London's Stroke Research Patient and Family Group (SRPFG) comprising 32 stroke survivors and carers also provided feedback on the design of the intervention in two of their meetings.

Data Analysis

Data from focus groups and interviews were audio recorded, transcribed in full and stored in NVivo (Version 11). Qualitative data were analysed using a thematic analysis approach⁴² to identify themes and sub-themes related to stakeholder perspectives informing the identification, design and evaluation of a DSS to improve secondary prevention for stroke survivors, which could be part of a LHS. This involved two authors (TP, ES) assigning codes and refining themes from the data, noting similarities and differences between stakeholder perspectives. The two authors have doctoral/post-doctoral experience in conducting and analysing qualitative data in applied health research.

RESULTS

Focus groups and interviews

Eight themes related to improving secondary prevention and management of multiple risk factors after stroke were identified from focus groups and interviews:

1. Involve stroke survivors in decisions concerning their treatments

In the focus groups, stroke survivors often articulated that due to their multiple health conditions, and hence multiple risk factors for stroke recurrence, they would like to be more involved in selecting their treatments based on what is important to them and their desired outcomes. This viewpoint was further confirmed by stroke survivors participating in King's College London's SRPFG. A number of clinicians perceived that SDM did not take place on a regular basis during routine clinical consultations, and there was a need for greater involvement of stroke survivors and their carers in selecting treatments that best meet their needs and preferences. Commissioners and policy makers agreed that SDM is a necessity and noted that policies in the UK and other countries required the involvement of patients in their treatment decisions. They also emphasised the importance of data and evidence-based recommendations to improve decision making about treatments.

"When I go to my doctor I realise it's my doctor who is making the decisions...but I think that patients now know often more about their own condition than the health professionals" (stroke survivor, SEM)

"This information (risk factors) which used to be something that I, as a doctor, only thought about, it's now something that we should think about together" (GP, FG5)

"How do we help patients and carers and health professionals together have a discussion using data information to make decisions about treatments?" (commissioner, FG2)

2. Present and communicate recurrent stroke risk in a meaningful way

Both stroke survivors and healthcare professionals (in the focus groups and interviews) emphasised the importance of displaying and communicating personalised stroke risk estimation in a clear and meaningful way. Stroke survivors expressed that current risk presentations lacked clarity, with healthcare professionals agreeing with this idea, reporting that they also find it difficult to understand and communicate risk to patients whilst linking it to specific actions and behaviours among patients.

“What is this individual’s risk of a further stroke in five years... and that’s really important because patients commonly ask us that ‘what is the risk of me having another stroke in the next year’ and we come up with a figure and we say ‘5% of whatever’” (hospital stroke physician, Interview)

“And I think the other thing is what actually is risk, how do you convey that, I mean, is it twice as much risk if I’ve never had a stroke...I know exactly what you mean 50% and 5% of that are meaningless to most people” (stroke survivor, FG4)

“Because the patients often think that the GPs – or the doctors/the specialists understand risk. It’s really difficult to understand risk and we have to use guidelines to help us with risk. So if the guidelines say, ‘This is a risk and this is the level at which you should intervene’, then I’m not well enough informed to go any further than that” (GP, FG3)

3. Compare stroke survivor’s perceived stroke risk with their predicted risk

In one of the focus groups, a carer voiced the importance of allowing stroke survivors to articulate their own perceived risk of having a recurrent stroke, which could then be compared with the actual predicted risk. Professionals and lay stakeholders in the group agreed that this would facilitate a collaborative discussion on potential risk factors and their impact on stroke risk.

“Patients themselves if they’ve been through a process will likely at some point be shown something and said either mark yourself on this, because another thing is where do you think you are on this scale at the moment with your risks, sometimes that’s quite powerful” (carer, FG4)

4. Personalise treatments to help control multiple stroke risk factors

Different stakeholders in a number of the focus groups and interviews emphasised the importance of controlling multiple risk factors for stroke recurrence in stroke survivors with multimorbidity and the need to develop effective treatments based specifically on the patient’s characteristics (e.g., age, ethnicity, health conditions). Stroke survivors from the SRPFG similarly voiced their preference to know their personal risk according to their personal characteristics and receive tailored advice from professionals about what specific actions they could perform to reduce the identified risks. Commissioners were interested in care pathways for stroke patients with multimorbidity and how these care pathways could be tailored to the patient’s characteristics.

“Patients who’ve had a confirmed stroke, the first thing as a family physician in terms of management is to make sure that you’ve controlled all their risk factors to prevent them getting another stroke” (GP, Interview)

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3 *“And if the system could provide him, like, tailored for the patient taking all the information*
4 *and saying OK for this patient because he had stroke, he has diabetes and high blood pressure,*
5 *we recommend the following care pathway, treatments” (commissioner, SEM)*
6

7 *“Anything that can be personalised or tailored, so you don't feel it's this off the shelf thing that*
8 *you're being given, you know... you sit with your doctor and it's not just a case of giving out a*
9 *leaflet, but actually let's have a look at your personal data” (occupational therapist, FG4)*
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11

12 **5. Display effectiveness of recommended treatments in reducing stroke risk**

13 The majority of health and social care professionals, commissioners and policy makers perceived that
14 stroke survivors with multimorbidity often have multiple risk factors to manage, and that prioritising
15 the different treatments available for secondary prevention of these risk factors was required. Stroke
16 survivors wanted to know the relative benefit of the proposed treatments being offered by clinicians
17 in terms of how they addressed stroke risks and to take this information into account when deciding
18 on personalised treatments. Commissioners specifically emphasised the importance of using
19 evidence-based data to prioritise treatments to help patients in their decision making.
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22 *“...and you need to know, in fact, what the risk is if you do nothing compared with the risk if*
23 *you do something” (stroke survivor, FG3)*
24

25 *“The question might be for a patient ‘should I take a statin after a stroke’ and we might be*
26 *able to use the database to answer the question ‘what would be the risk of future stroke if I do*
27 *take a statin or if I don't take a statin’ and you can use that information to help to come to a*
28 *decision together” (commissioner, SEM)*
29
30

31 *“Well I suppose you could think about the common comorbidities, so hypertension and stroke,*
32 *AF (atrial fibrillation) and stroke, diabetes and stroke and you could think about not necessarily*
33 *an algorithm but a sort of stepwise prioritisation about what you should think about in terms*
34 *of the patient's total management, you know, which would be the most important area of*
35 *focus?” (GP, Interview)*
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40 **6. Address stroke survivor concerns about treatment and barriers to adherence**

41 Stroke survivors in some of the focus groups and the members of the SRPFG raised concerns about
42 the challenges of multiple treatments they were expected to adhere to in order to decrease the
43 potential risks of a recurrent stroke, commonly reporting that they did not always understand the
44 value of these treatments. Several felt that a joint discussion with a healthcare professional about
45 these concerns would help them better understand the value of a particular treatment and reach an
46 informed decision about it. When interviewed, several GPs agreed that it was very challenging for
47 stroke survivors with multimorbidity to adhere to multiple medications and other treatments at any
48 given time, and that it is sometimes difficult to identify among their various treatments what is
49 absolutely necessary and what is ‘good to have’.
50
51

52 *“My experience both with the doctors at the surgery and the consulting hospital is trying to*
53 *discuss the medication that they insisted I took. I had horrendous side-effects and I kept trying*
54 *to say to them ‘Look, I'm having these side-effects, can I change, can I reduce, can I do blah*
55 *blah’ and their attitude I have to say, is one of terrorising patients” (stroke survivor, SEM)*
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3 *"I think that's a common problem with all patients that suffer from comorbidities. It's*
4 *rationalising their medication and you know being able to take a holistic view of the person*
5 *and make sensible decisions about what they absolutely need to continue on and what they*
6 *don't. And you can only really do that just by having time with the patient, you know if it's*
7 *important for them to be able to sort of get up and get out and about and not feel dizzy, then*
8 *you may have to compromise on how much blood pressure medication they take" (GP,*
9 *Interview)*

13 7. Support continuity of care

15 Stroke survivors commonly reported that they do not have appointments with their GP or other
16 healthcare professionals on a regular basis. Several felt that the idea of personalised care to control
17 stroke risk factors is very important but should have a follow-up to ensure continuity of care, which
18 was often lacking. Some also perceived that the selected treatments and management plan should be
19 saved on the system for future consultations and a follow-up appointment always set in advance.
20 Commissioners also emphasised the importance of follow-up appointments and raised the concern
21 that although follow-up appointments are an important part of stroke management and are required
22 according to the National Institute for Health and Care Excellence (NICE) guidelines, many stroke
23 survivors do not have follow-up appointments and do not see a GP over the longer term.

27 *"I'm just thinking of my practice where it's very difficult to get to see the same doctor and if I*
28 *was presented with my third in line (i.e. the risk graphic display) ten times from ten different*
29 *doctors I'd be starting to get a bit hacked off I think" (stroke survivor, FG4)*

31 *"It's not a one time thing...there needs to be continuous interaction I think if something's going*
32 *to happen (stroke survivor, FG4).*

35 8. Identify stroke survivors at high risk of recurrent stroke

37 Healthcare professionals, commissioners and policy makers highlighted the need to proactively
38 identify stroke survivors at high risk of having a recurrent stroke to assess and treat them in a timely
39 manner. They felt that many stroke survivors, especially those with more severe long-term
40 consequences from the stroke, do not often see a physician, and it is important to have a smart
41 (automatic) system in place that could proactively identify them and assess their risks.

44 *"I think the challenge first of all who are the high-risk patients, can we identify them and, if we*
45 *can, is there a way through case management or community matrons, you know, linked with*
46 *the stroke teams in the community providing access to therapy and assessment when it's*
47 *required in a timely fashion" (commissioner, Interview)*

50 Development of DOTT decision aid

51 The above themes and solutions were proposed, designed and refined during the collaborative design
52 process with stakeholders, which informed the design of DOTT (Deciding on Treatments Together).
53 DOTT is a computerised decision aid (i.e., a DSS designed to facilitate SDM), integrated with the EHR
54 system, to be used in primary care during clinical consultations between the healthcare professional
55 and stroke survivor, aiming to facilitate SDM on treatments to reduce recurrent stroke risk.

57 Specifically, DOTT will:
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4 (1) Allow stroke survivors to indicate, in a graphic presentation (Figure 2), **their perceived risk of**
5 **having a further stroke**. The graphic presentation in DOTT is based on population rank^{43,44}
6 simulating a queue of 20 people around the same age of the stroke survivor. Stroke survivors
7 indicate where they think they are positioned in the queue (from least to most likely). This risk
8 would then be compared to the actual predicted risk to facilitate conversation on risk factors.
9 Needs from theme 3 are addressed with this feature.
10
- 11 (2) Display **stroke survivor's predicted risk of having a further stroke** in a meaningful and
12 understandable way for both healthcare professionals and stroke survivors. For the usability
13 evaluation, the system displayed a 'typical' recurrent stroke risk based on age³⁷. The final
14 personalised stroke risk model is under development and will be calculated based on the patient's
15 information from the EHR and on rules generated from the linked dataset (SLSR and LDN). This
16 will include variables such as age, gender, medical history (e.g., hypertension, atrial fibrillation),
17 type of stroke and time since stroke. Needs from theme 2 are addressed with this feature (see
18 Figure 2).
19
- 20 (3) Provide a **list of personalised recommended treatments** for stroke survivors based on their risk
21 factors (e.g., hypertension, atrial fibrillation) extracted from the EHR. A list of the most effective
22 evidence-based treatments for secondary prevention would be compiled and extracted from the
23 recent NICE guidelines⁴⁵ and the National Clinical Guideline for Stroke.⁴⁶ This includes both clinical
24 and lifestyle recommendations. For each recommended treatment, the evidence supporting the
25 treatment will also be displayed. Needs from section 4 are addressed with this feature.
26
- 27 (4) **Prioritise the recommended treatments** based on their relative risk reduction and present the
28 most effective treatment first. The clinician and stroke survivor can select one or more treatments
29 and see on the graphic display, how the treatments reduce the overall stroke risk. The benefit of
30 each treatment in terms of stroke risk will be calculated using the linked dataset (SLSR and LDN).
31 Needs from theme 5 are addressed with this feature.
32
- 33 (5) **Display stroke survivors' common concerns** on the suggested treatments (e.g., "do I have to take
34 blood pressure drugs for life?"), which will aid in identifying and addressing barriers to treatment
35 adherence and eliciting preferences. An initial list of concerns and their response was prepared
36 based on qualitative studies eliciting patients' barriers to treatment adherence.^{47,48} Needs from
37 theme 6 are addressed with this feature
38
- 39 (6) Allow stroke survivors and their carers to discuss the different treatments with the healthcare
40 professional and **jointly select the treatments that best suit the stroke survivor's preferences,**
41 **desired outcomes and goals** (and remove the ones that do not). Lifestyle modification will be
42 discussed during the consultation and enhanced through referral to specialists or lifestyle
43 intervention programs. The agreed management plan and information on the different
44 treatments will be printed and handed to the stroke survivor to take home. Needs from theme 1
45 are addressed with this feature.
46
- 47 (7) Set automatically a **follow-up appointment** in 3 months' time. The information entered, including
48 the agreed management plan is saved and transferred back to the stroke survivor's EHR for future
49 consultations. During the follow-up consultation, the management plan is reviewed and
50 treatments to address risk factors for stroke recurrence can be added, modified or removed.
51 Desired clinical and patient outcomes will also be reviewed. Current NICE guidelines⁴⁵ for
52 'Secondary prevention following stroke and TIA' recommend primary care follow up on discharge,
53 six months and then annually. A three-month follow up was selected as a reasonable interval for
54 healthcare professionals and to provide enough time for patients to adhere to the selected
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3 treatments. Needs from theme 7 are addressed with this feature.

- 4 (8) The stroke prediction model will also be used to **proactively identify individuals at high risk of a**
5 **recurrent stroke** by calculating their recurrent stroke risk at defined periods of time (the practice
6 can define the desired threshold) and alert the practice (e.g., physician, nurse, receptionist) to
7 invite those patients for a clinical consultation. Needs from theme 8 are addressed with this
8 feature.
9
10 (9) All information from patients and healthcare professionals (e.g., treatments selected by the
11 patient, desired outcomes, predicted stroke risk, results in follow-up) will be **captured by the**
12 **system as part of a LHS** and be used to improve the system's predictive model and treatment
13 recommendations.
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16
17 Figure 2 depicts an example screenshot from DOTT decision aid prototype.

18
19 <Insert Figure 2 here>

20 21 Usability and acceptability evaluation

22 23 Demographics

24
25 Eight stroke survivors and eight GPs participated in the usability and acceptability evaluations. GPs (4
26 men, 4 women) had average of 10.3 years of experience as a GP. All had experience in providing care
27 to stroke survivors, had medium to high confidence in using new technology and low to medium
28 experience using DSS. Stroke survivors (4 men, 4 women) had an average age of 65.5 years (SD: 11.4,
29 range: 49-81). All had hypertension, two had heart problems, one was suffering from depression, four
30 had mobility issues, and four had minor cognitive deficiencies (attention and memory).
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33 34 Usability and acceptability

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36 Both GPs and stroke survivors found the decision aid usable and acceptable. GPs found the decision
37 aid easy to use (score 4.3), easy to understand (4.1) and felt very confident using it (4.2). They thought
38 that this decision aid was better than how they usually helped patients decide about treatments for
39 controlling their risk factors (4.4), that this strategy was compatible with the way they thought things
40 should be done (4.3), that this type of decision aid was suitable for helping patients make informed
41 choices (4.0) and that the decision aid complemented their usual approach (4.4). Stroke survivors
42 perceived that they would like to use the decision aid frequently (4.0), thought that it was easy to use
43 (4.2) and felt confident using it (4.1). Initial findings of the usability evaluation can be found in Porat
44 et al.⁴⁹
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48 49 Identified themes

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51 Seven main themes relating to the usability and acceptability of the decision aid were identified. These
52 were divided into themes relating to the importance of the decision aid, its functionality and concerns
53 from using it.
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Importance of the decision aid

Logical and structured process that facilitates discussion

All GPs and stroke survivors (N=16) found the decision aid to be clear, and consisting of a logical flow that helped to structure the consultation. They felt that the decision aid facilitated a transparent discussion on the different proposed treatments and elicited patients' preferences.

"Physician pointing out what to do but the patient makes the decision since it's hard to get your head around everything. More doable if you have specific areas to work on with specific targets that suits you" (stroke survivor 2)

Importance of a learning system

Several GPs (N=3) raised the importance of a learning system providing up-to-date information. They wanted to make sure that the suggested treatments are in line with the most up-to-date evidence.

"The learning aspect is very important, since this system is based on evidence and evidence can change" (GP 6)

Can motivate patients to change behaviour

All GPs and stroke survivors (N=16) believed that the decision aid could motivate patients to change behaviour (e.g., take their medication to reduce blood pressure, increase physical activity, eat healthy). Stroke survivors liked the idea of being involved in deciding on their treatments according to their preferences and abilities, receiving information on their stroke risk factors, and discussing their views and concerns with their GP. They felt it gave them more control over their health and motivation to adhere to the treatments they selected. GPs felt it was a good way to discuss the different treatments and give patients the power to decide on treatments that suit them. A number of GPs and stroke survivors agreed that sharing decisions and enabling patients to select the treatments that best meet their preferences and goals, may increase patients' feeling of ownership over their health and improve adherence to the selected treatments.

"I believe discussing the different options with the patients, shared decision making, is likely to improve adherence" (GP 1).

Functionality

Powerful risk display showing the benefit of each treatment

The vast majority of GPs and stroke survivors (N=15) found the visual display showing the risk before and after a selected intervention, easy to understand, with some viewing it as a 'powerful' tool. Both stroke survivors and GPs commented that they were not aware of the effect the treatments have on reducing the stroke risk.

"The most powerful thing is the visual shifting of risk" (GP 5)

"Wow, a small change can make a big difference, this is very encouraging" (stroke survivor 6)

The patient takes home printed information

GPs and stroke survivors (N=10) thought that it was very important that the patient has a copy of the management plan and all the information printed so they can review it at home. In particular, stroke survivors wanted to have their current predicted risk and information on their selected treatments,

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3 including the date of the follow up appointment printed out, so it could motivate them to adhere to
4 their treatments.
5

6 *“The important thing is that the patient goes out with a piece of paper that summarises in*
7 *bullet points the outcome of the consultation. If its black and white on paper it makes a*
8 *difference” (stroke survivor 3)*
9

10 Concerns

11 GPs and stroke survivors raised two main concerns from using the decision aid.

12 Deals with one aspect of the consultation

13 GPs and stroke survivors (N=6) felt that the decision aid is good but focuses on one aspect of the
14 consultation (reducing risk of recurrent stroke) and patients may have other concerns, such as
15 depression or social isolation.
16

17 *“This is good, but for me the most important thing is the emotional aspect, and this tool*
18 *doesn’t relate to that” (stroke survivor 4)*
19

20 Time

21 The main concern for GPs was time (N=6), in which within the allotted standard 10 minutes for the
22 consultation already provided significant limits, and most felt they will not manage to fit it in.
23

24 **Suggestions for improvement**

25 GPs and stroke survivors provided suggestions for improving the decision aid:

- 26 1. The terminology was too clinical, for example “treatments” and “management”, could be
27 changed to “possible strategies or approaches”.
- 28 2. In addition to the management plan, information (e.g., in the form of a leaflet) on each of the
29 selected treatments should also be printed out and given to patients.
- 30 3. Add clinical data, for example when clicking on “cholesterol” show the patient’s last three
31 values, and do this also for their blood pressure.
- 32 4. Enable more than one display of risk, because each patient may prefer a different display and
33 understands risk differently.
- 34 5. Add emotional and mental health aspects which are related to stroke risk.
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44 We subsequently made the above changes and additions to the updated version of DOTT.
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46 **DISCUSSION**

47 Our work focused on engaging various stakeholders in the identification, design, prototyping and
48 evaluation of a decision aid to improve secondary prevention after stroke. Eight themes informed the
49 design of DOTT. A number of the themes and solutions proposed by the stakeholders have been
50 implemented previously to some extent to support other patient groups, such as diabetes and atrial
51 fibrillation.^{50,51} These include, predicting a patient’s risk based on their risk factors, proposing possible
52 treatments and displaying their benefit in decreasing the risk⁵⁰ and incorporating patients’ concerns
53 within the decision making process.⁵¹ These themes were found useful and are recommended in SDM
54 tools (e.g., in the IPDAS²³).
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3 Additional unique themes and solutions have emerged as outcomes of the collaborative design
4 process in this study, which could be used for a range of chronic diseases requiring long-term
5 management. Specifically:
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8 (1) **Present and communicate risk in a meaningful way.** While there are many different ways to
9 communicate multiple risks to patients, the most commonly used are absolute or relative risks
10 presented as percentages or probabilities (e.g., “from 100 people like you 20 are expected to have a
11 recurrent stroke”).⁵² However, studies have shown that in general, healthcare professionals are as
12 unfamiliar as their patients with risk estimates and probabilities⁵³ and often healthcare professionals
13 have reported finding it difficult to combine multiple risk factors into an accurate assessment of
14 vascular risk⁵⁴ and to communicate this risk to patients.⁵⁵ Moreover, patients may feel that statistical
15 risk estimates do not apply to them personally.⁵⁶ To overcome this, our graphic presentation is based
16 on population rank, simulating the patient in a queue of people around their age.^{43,44} Studies have
17 also shown that formats which present data framed as the risk of an individual were perceived as
18 more relevant and easier to relate to than percentage risk estimates.⁵⁷
19

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21
22 (2) **Compare patient’s perceived risk with their predicted risk.** This is a novel requirement from a DSS,
23 which to our knowledge does not exist in current systems. Perceived risk of adverse outcomes such
24 as stroke may be an important concept in understanding patient’s adherence to medication and
25 recommended health behaviours.⁵⁸ Overall, patients tend to underestimate their own risk.⁵⁹ This
26 tendency was also found when patients estimated their cardiovascular risk.⁶⁰ Weinstein refers to this
27 underestimation as an “optimistic bias”.⁵⁹ For example, a recent study found that people with
28 undiagnosed diabetes or prediabetes considerably underestimated their probability to have or
29 develop diabetes.⁶¹ Lower perceived risk has been associated with poorer adherence to
30 recommended health behaviours⁶² and hence a more realistic perception of risk may increase
31 patients’ interest in risk reduction.⁶² Research has shown that individualised risk feedback was
32 effective in increasing perceived stroke risk among patients who had underestimated their stroke risk
33 at baseline.⁶³ This may imply that eliciting patients’ perceived risk and showing them the actual
34 predicted risk, can change their inaccurate risk perception and increase their interest in risk reduction.
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38 (3) **Prioritising treatments.** Healthcare professionals have previously expressed concerns about
39 managing care and making decisions about treatments, including communicating risks and benefits
40 for patients with multimorbidity and complex needs.⁶⁴ They commonly report having to make
41 decisions with such patients which involve a process of prioritisation or trade-offs, facilitating a
42 discussion with the patient on what is important to the patient and what they would like to achieve
43 in terms of their health (i.e. goal setting).⁶⁴ Aligning patient goals and desired outcomes with clinicians’
44 goals is likely to improve outcomes for these patients.⁶⁵
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48 (4) **Identify individuals at high risk.** Calculating periodically (in an automatic way) the stroke risk of
49 survivors to identify individuals at high risk of recurrent stroke (based on their information in the EHR)
50 could be a valuable feature for improving long-term management and care for stroke survivors who
51 are less likely or able to visit healthcare professionals on a regular basis. This theme was identified and
52 prioritised by healthcare professionals and commissioners/policy makers and not by stroke survivors
53 or carers, emphasising the importance of treating vulnerable patients in a timely manner and provide
54 proactive patient-centred care. This is in line with the NHS Long Term Plan set in 2019.⁶⁶
55 Patients/carers who participated in the focus groups were relatively mobile and maybe this was less
56 of a priority for them.
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3 These solutions, which are delivered through a DSS integrated with the EHR system and based on data
4 from a linked population dataset, have the potential to be an instrument of change in clinical practice.
5 This will be done by providing scientific evidence at the point of clinical care (e.g., personalised
6 treatments and their benefit based on the individual's risk factors), while simultaneously collecting
7 information from that care (e.g., treatments selected by the patient, desired outcomes, predicted
8 stroke risk) to promote innovation in optimal healthcare delivery.¹⁷
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11 **Strengths and limitations**

12 Although the core focus of the DSS (prevention of a future stroke) was identified by patients as a
13 priority, having a single focus might hinder discussions of other important problems (e.g., depression,
14 social isolation). Such issues may even have a larger perceived impact on long-term outcomes after
15 stroke, for example, improving mental health or access to social care services, which were also
16 brought up by stakeholders as a priority to address long-term care for stroke survivors with
17 multimorbidity,¹⁴ and were raised as a concern in the usability and acceptability evaluations.
18 Depression is indeed a risk factor of stroke,⁶⁷ and the treatment 'manage low mood/depression' will
19 be displayed to all patients, enabling healthcare professionals to relate to this aspect and propose
20 ways to manage this (e.g., medication, referral to a professional, group therapy).
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22

23 In a study assessing stroke survivors' self-reported needs,⁶⁸ more than 50% of long-term stroke
24 survivors reported an unmet need for stroke information (e.g. cause, prevention of recurrence). The
25 proposed decision aid offers a meaningful starting point for addressing this common unmet need.
26 Evidence suggests that the provision of lifestyle advice from healthcare professionals' is effective in
27 changing health behaviours⁶⁹ and healthcare professionals' communication is positively correlated
28 with patient adherence to treatments.⁷⁰ However, a conversation-based DSS also relies on the
29 attitudes and communication skills of the healthcare professionals, which have been found to vary.⁷¹
30 Interactive SDM skill training has improved SDM skills and promoted positive attitudes.⁷² Training
31 healthcare professionals in communication skills for SDM has also been shown to result in substantial
32 and significant improvement in patient adherence to treatments.⁷⁰ Hence, interactive SDM skills
33 training workshops will have to complement the use of the DSS. Patients are also likely to need support
34 and preparation with taking part in SDM during the consultation.⁷²
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37 The design of DOTT meets the IPDAS collaboration criteria for quality decision aids.²³ Specifically, DOTT
38 was designed to incorporate principles of SDM, by presenting stroke survivors with information about
39 their treatment options and likely outcomes, presenting the risks and benefits of each option, and
40 engaging the healthcare professional and stroke survivor in a joint conversation about the patient's
41 preferences.³² Furthermore, DOTT evolves from a systematic development process, uses non-
42 technical language and presents information in a balanced manner that allows for comparisons across
43 alternatives.²³ Wearable sensors (e.g., Fitbit, Apple Watch, blood pressure monitor) could further help
44 patients monitor and self-manage the selected treatments (e.g., control blood pressure, increase
45 physical activity) outside the consultation. In the future, data from wearable sensors could be
46 integrated to the EHR, and DOTT could use this information to improve its risk prediction model and
47 treatment recommendations.
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50 In the usability and acceptability evaluation, stroke survivors and GPs found DOTT to be both useful
51 and usable. GPs perceived that the decision aid helped with structuring the consultation and eliciting
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3 patients' preferences for treatments. Stroke survivors felt it provides a good way to understand the
4 different treatment options and select the ones that best suits their preferences. GPs' main concern
5 was that the decision aid would increase consultation times. Indeed, time constraints were identified
6 as the main barrier for the adoption of innovations by family physicians.^{73,74} A possible solution could
7 be to use the decision aid as part of a clinical review after stroke, which is usually longer (e.g., 3 month,
8 6 month and annual review) and by dedicated healthcare professionals which are less limited in time
9 such as stroke nurses and pharmacists working in GPs' practices that are trained to consult patients
10 with chronic and long-term health conditions.
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14 CONCLUSION

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16 Engaging various stakeholders throughout the design and evaluation process ensures that the
17 intervention (features and functions) is in line with the needs reported by the different stakeholders
18 (i.e., stroke survivors, healthcare professionals, policy makers). DOTT has demonstrated the potential
19 to reduce stroke recurrence by adopting a data-driven user-centred approach. DOTT urges clinicians
20 to shift away from the professionally led advice-giving approach typically used in medical
21 consultations to one which collaboratively and actively engages the patient in decision making and
22 respects patient choice and autonomy. This may lead to stroke survivors taking ownership for the
23 treatment decisions, improving their adherence to the agreed management plan and thus reducing
24 their stroke risk. A future feasibility study and subsequent clinical trial will evaluate the effectiveness
25 of DOTT in improving decision making quality, and whether it affects risk factor levels and risk of
26 recurrence. While DOTT currently targets stroke risk factors only, the design approach and its features
27 could be used for a range of chronic diseases requiring long-term management, paving the way to a
28 set of standards for delivering LHS interventions in clinical practice.
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35 the study including stroke survivors, carers, healthcare professionals, policy makers and
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43 CDAW, VC. Sign off final version of manuscript: TP, IM, ES, MAV, CK, CDAW, VC.
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45

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55

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Figure captions

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Figure 1: A diagrammatic summary of the development and evaluation of DOTT, including the data that fed the different stages and the outputs. SEM = Stakeholder Engagement Meeting (consisting of 3 focus groups); FG = Focus group; SH=Stakeholders; IPDAS = International Patient Decision Aids Standards²³; SDM model = Shared decision making model for clinical practice³²; SRPFG = Stroke Research Patient and Family Group³¹

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Figure 2: An example screen from DOTT prototype displaying the stroke survivor's predicted stroke risk before and after a selected treatment (e.g., control of blood pressure).

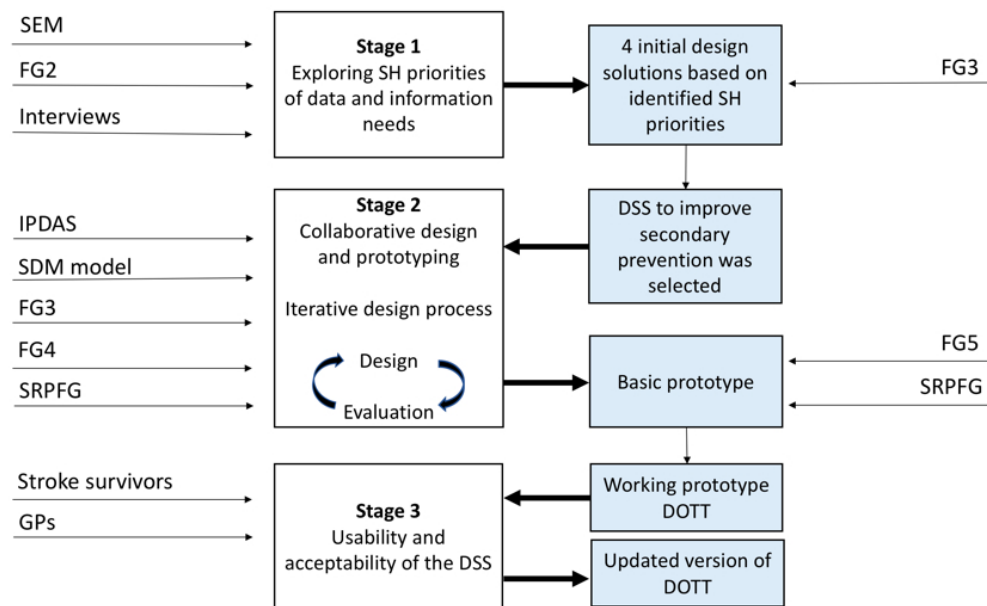


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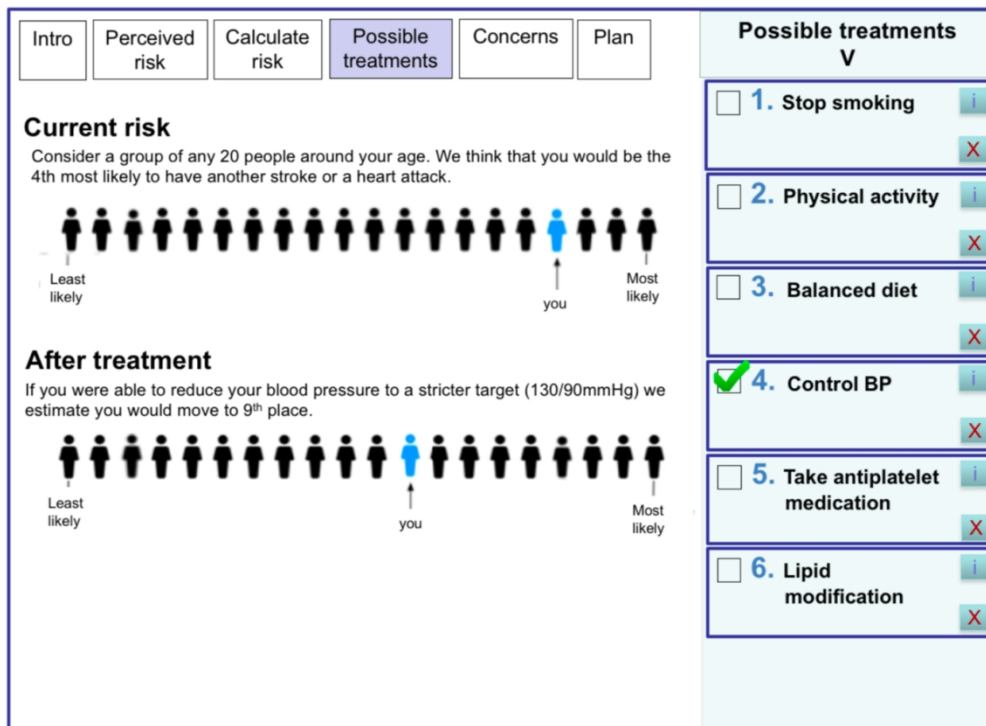


Figure 2: An example screen from DOTT prototype displaying the stroke survivor’s predicted stroke risk before and after a selected treatment (e.g., control of blood pressure).

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3 **Box 1: Topic guide for the separate focus groups in the SEM**
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5 In a large group, explain:

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- 7 • Study aim
 - 8 • What a LHS is, and how a LHS might work in general practice
 - 9 • The co-production approach we are using
- 10

11 In separate focus groups:

- 12
- 13 • Ask participants to provide examples of information which are/would be useful for
 - 14 patients/carers/clinicians/health commissioners?
 - 15 • Previous experiences of information delivery: What worked well? What worked badly/not so
 - 16 well?
- 17

18 Explore stakeholders' understandings around what is data linkage, and what is a learning health
19 system (LHS)?

- 20
- 21 • How would a LHS work in practice for stroke?
 - 22 • Any ethical concerns about this process (particularly regarding data linkage)? How can these be
 - 23 addressed?
 - 24 • What types of information could be generated using this method?
 - 25 • How broadly might they be delivered?
- 26
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29 Discuss ideas for new information interventions

- 30
- 31 • Feedback from individual groups
- 32

33 Develop as a larger group a priority list for key priorities for data and information needs.

34 Note: Since a few healthcare professionals could not attend the focus groups, we conducted face-to-
35 face interviews with them using the same topic guide.
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4 Box 2: post-usability interview - patients

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- Do you have any comments about today's session? Feel free to comment on anything you want.
 - How did it feel having a consultation using the decision aid?
 - Who do you think should be involved in making decisions about how acceptable your risks are of having a further stroke?
 - your doctor alone
 - mostly your doctor
 - your doctor and you equally
 - mostly you
 - you alone
 - Who do you think should be involved in making decisions about ways to reduce your risk of stroke?
 - your doctor alone
 - mostly your doctor
 - your doctor and you equally
 - mostly you
 - you alone
 - To what extent do you agree with the following statement? (from 1 strongly disagree to 5 strongly agree)
 - The decision aid will help patients with adopting healthier behaviours, such as changing Lifestyle habits and/or taking medication according to the management plan they agreed on.
 - Having seen how the decision aid works, patients will likely look for more information about stroke and its risk factors.
 - (if agreed on statement above) Can you please describe how the decision aid might support patients in changing some of their health-related habits?
 - What might make it difficult (barriers, hurdles) for patients to change some of their health-related habits?
 - Would you find the decision aid helpful for your own health-related habits?
 - What do you like about the decision aid?
 - What don't you like about the decision aid?
 - What suggestions do you have to improve the decision aid?

49 Give Acceptability and Usability questionnaires.
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