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Title

Developing a Fatigue Programme: Protocol for the Nottingham Fatigue After Stroke (NotFAST2) Study.

Short title

Nottingham Fatigue after Stroke Study 2.

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19 **Research Ethics**

20 Ethical approval has been granted by the University of Nottingham, Faculty of Medicine and Health
21 Sciences Research Ethics Committee (Reference 480-2001, 10 March 2020).

22

23 **Declaration of conflicting interests**

24 The Authors confirm that there is no conflict of interest.

25

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32

33

34

1 **Abstract**

2

3 **Introduction:** Post-stroke fatigue (PSF) is common and is one of the most distressing symptoms after
4 stroke. It has a negative impact on physical, social and psychological functioning: it is also associated
5 with poor outcomes and increased mortality. The effective management of PSF is therefore
6 regarded as a clinical priority.

7

8 **Method:** Mixed-methods design with three overlapping phases. *Phase 1* will be a survey of existing
9 fatigue management within the UK. In *phase 2*, interviews and focus groups will be conducted with
10 stroke survivors with fatigue, carers and clinicians to determine strategies used to manage fatigue
11 successfully. In *phase 3*, data from phases 1 and 2 will contribute to the co-design of a fatigue
12 management programme with the [NotFAST2] study Patient and Public Involvement group. This will
13 be further refined through subsequent focus groups which will include those with fatigue associated
14 with other health conditions.

15

16 **Results:** Survey data will be analysed using descriptive statistics. Interview and focus group data will
17 be analysed using a framework approach.

18

19 **Conclusion:** PSF requires a comprehensive management programme necessitating input from key
20 stakeholders. A PSF programme will be developed which will be tested in a future randomised
21 controlled trial.

22

23

24 **Keywords:**

25 protocol

26 post-stroke fatigue

27 fatigue management

28 stroke

29 self-management

30 community

31

32

1 **Introduction**

2 Post-stroke fatigue (PSF) is an ‘overwhelming feeling of exhaustion or tiredness’, which is not related
3 to exertion, and which does not typically improve with rest (De Groot et al, 2003). PSF is common,
4 and affects 50% of people after their stroke (Cumming et al, 2016; Hinkle et al, 2017). It is
5 distressing for the stroke survivor (Van der Werf et al, 2001), linked to poor outcome such as
6 disability, depression and lower quality of life (Lerdal and Gay, 2017), increased mortality (Glader et
7 al, 2002), and contributes to significant carer burden (Mandiliya et al, 2016). PSF can occur in those
8 who have made an otherwise good recovery and can occur early after stroke, or later (Hawkins et al,
9 2017) and can affect all aspects of daily life (Worthington et al, 2017). However, the effect of fatigue
10 is most likely to be noticed when people are discharged from hospital and are back in their own
11 homes. The management of PSF is recognised as an ongoing national and international research
12 priority (Norrving et al, 2018).

13
14 Although researchers have endeavoured to explain PSF mechanisms (De Doncker et al, 2018), these
15 remain unclear. This may be due, in part, to the lack of a single, accepted and widely adopted
16 definition of post-stroke fatigue (Barker-Collo et al, 2007; Thomas et al, 2019) and also because of
17 misunderstanding around the use of key terms such as fatigue and tiredness (Thomas et al, 2019).
18 It is known that there are many contributing factors (Mandiliya et al, 2016; Cumming et al, 2016; Aali
19 et al 2020) and it would seem that each research team previously has concentrated on specific
20 issues: exercise, sleep, nutrition, medication and psychological interventions. In an attempt to
21 evaluate the overall evidence, several comprehensive reviews (Hinkle et al, 2017; Aali et al, 2020)
22 and Cochrane systematic reviews (Kennedy and Kidd, 2018; Wu et al 2015) have compared findings
23 from randomised controlled trials (RCTs) and clinical studies of PSF to draw overarching conclusions.
24 All the reviews to date have concluded that there is insufficient evidence of the efficacy of the tested
25 interventions in trials, and that more robust research with adequate sample sizes is required. For
26 example, in the review conducted by Wu et al (2015) the authors reported a pooled SMD of -1.07
27 (95% confidence interval (CI) -1.93 to -0.21) in favour of reducing fatigue with interventions in the
28 studies they included. However, this benefit was not found when data from the more rigorous
29 studies were examined: SMD -0.38 (95% CI -0.80 to 0.04) with adequate allocation concealment and
30 SMD -1.10 (95% CI -2.31 to 0.11) with appropriate blinding of assessors. The results from the studies
31 and reviews demonstrate the need for more research into PSF and underline the need for this
32 research to be more robust and better designed.

33

1 Consequently, current clinical practice guidelines rely on low levels of evidence, such as expert
2 consensus, to make recommendations for PSF. There are therefore few specific recommendations in
3 UK (Royal College of Physicians, 2016) or other international clinical guidelines (e.g. Australian
4 National Stroke Foundation, 2010) for its management. Broadly, international expert consensus
5 supports assessment and information provision, the provision of rehabilitation during periods of
6 lower fatigue, pacing of activity, exercise and advice on sleep (Lanctot et al, 2019). It is suggested
7 this improves outcome and quality of life of stroke survivors as well as reducing caregiver burden.

8
9 In the absence of definitive guidance, and with an incomplete evidence base, our aim is to conduct a
10 study to develop a fatigue management programme for stroke survivors with PSF. We will not
11 concentrate on one aspect of management but instead will take a comprehensive but pragmatic
12 view and collect data from experts: stroke survivors, carers (that is, unpaid carers who are likely to
13 be family or friends) and clinicians. We will collect data on both PSF strategies and on approaches
14 used in fatigue management more broadly. We have conducted a comprehensive scoping review
15 (Aali et al, 2020) on PSF to inform our research proposal. The specific objectives are to:

- 16
- 17 • understand and document existing key management practices for PSF.
 - 18 • gain insights from the experiences and expertise of those who have fatigue, those who have
19 had help to manage it or those who offer support.
 - 20 • Utilise findings to co-design a community post-stroke fatigue management intervention.
- 21

22 We envisage that the proposed programme could be evaluated in a future, appropriately powered
23 randomised controlled trial.

24

25 **Methods**

26

27 **Ethics.**

28 Ethical approval was granted by University of Nottingham, Faculty of Medicine and Health Sciences
29 Research Ethics Committee (Reference 480-2001, 10 March 2020).

30

31 **Design**

32 This is a mixed-methods study, with three overlapping phases.

33

34 **Phase 1: Survey.**

1 We will conduct a survey of fatigue management provision within the UK. We will particularly focus
2 on stroke but will collect relevant data on other conditions where fatigue is a key symptom (for
3 example, multiple sclerosis, rheumatoid arthritis). We will examine eligibility criteria for referral to a
4 health professional or a service for fatigue management and examine the format and content of
5 interventions currently available. We will collect data on whether fatigue assessments are routinely
6 used, whether there is any routine follow-up provided and whether there are any differences in
7 management for post-stroke fatigue as compared to fatigue management in other conditions.

8

9 Data will be collected by contacting allied health professionals (AHPs), psychologists, doctors and
10 nurses through professional networks, Special Interest Groups and via social media. We will ask
11 colleagues to forward details of the survey to others with an interest in fatigue (snowballing
12 method). The research team will also use professional contacts to alert clinicians to the survey.
13 Participants will be eligible if they are clinicians from hospital or community fatigue services or who
14 have an interest/expertise in fatigue management in PSF or in other long-term conditions. The
15 survey will be available to complete online or can be returned by post. The aim will be to obtain as
16 many responses as possible over a three-month period.

17

18 **Phase 2: Interviews and focus groups.**

19 Interviews and focus groups will be conducted with stroke survivors with fatigue, carers and
20 clinicians about their experiences and strategies used to successfully manage fatigue. We will use
21 both face to face interview and focus groups because both formats have been found to
22 provide different and enriched data (Lambert and Loiselle 2008) and also provide participants
23 with choice. Participants will either participate in focus groups or semi structured interviews.

24

25 For stroke survivors and carers, we intend to use a multi-pronged approach to advertising the
26 study: locally and regionally -posters and flyers in the community and in GP surgeries,
27 community hospitals, stroke units and outpatient departments, local stroke clubs, community
28 centres and through existing national UK impatient networks (such as stroke lay conferences)
29 and through social media. A maximum variation sampling strategy (Palinkas et al, 2015) will be
30 used to ensure we capture a broad range of experiences such as age, gender, time since
31 stroke, ethnicity and geographical location. We want to be as inclusive as possible, and we will
32 therefore include people with aphasia.

33 Interviews and focus group discussions, based on participant preference, will be conducted with
34 stroke survivors with fatigue, carers and clinicians. We expect to achieve data adequacy (based on

1 similar previous studies) by conducting interviews with up to twenty stroke survivors with fatigue,
2 ten carers and 20 clinicians. However, our sample size will ultimately be guided by achieving data
3 saturation. Two focus groups with six to eight participants in each will be conducted. Participants will
4 be eligible if they are willing to give written informed consent and meet the following study criteria:

- 5 • **Stroke survivors** - have a diagnosis of stroke, are aged 18 years or over and have (or have
6 had) self-defined PSF. They will be excluded if they have a previous significant history of
7 fatigue before stroke- as defined by themselves.
- 8 • **Carers**- lives with and provides care (physical or psychological) for a stroke survivor with
9 fatigue and is 18 years or over. These are non-paid carers who are likely to be family
10 members or friends.
- 11 • **Clinicians**- are a registered nurse, doctor, psychologist or AHP, working in a service providing
12 fatigue management and/or have a recognised interest/expertise in fatigue management
13 broadly and/or in post stroke fatigue specifically. We will include international experts
14 where possible for the interviews.

15 All interviews and focus groups will be semi-structured, and will use interview and focus group topic
16 guides with key issues relating to fatigue informed by our recent, wide ranging review of the
17 relevant literature (Aali et al, 2020). The interviews will be conducted remotely via (Skype/video
18 conference/telephone) or face-to-face, depending on location, time availability and preferences of
19 participants and the research team. Focus groups will be held in an easily accessible location such as
20 on university premises or using virtual groups using telephone or video conferencing. In order to
21 keep an accurate record, all interviews and focus groups will be audio recorded, transcribed
22 verbatim and anonymized. The research team will also produce a contemporary field note after
23 completion of each interview and focus group.

24
25 For stroke survivors and carers our focus will be to collect data on: individual experiences of having
26 fatigue; history and onset of fatigue; characteristics of the fatigue; what helped and what made it
27 worse; and exploring any professional support and, or, information and whether it was useful or
28 not. We are also keen to determine what, in the participants' opinions should constitute best
29 practice for addressing PSF in the absence of clinical recommendations. In any instance where we
30 have a survivor-carer dyad, we will not have both in the same group: previous experiences have
31 suggested this may prevent individuals from speaking freely.

1 We will also interview 20 clinicians with an interest or recognised expertise in fatigue. We have
2 opted largely for interviews for this group because it may be difficult to bring clinicians together
3 for focus groups. However, we will endeavour to do this as well. We also want to include those
4 with expertise in fatigue-related other conditions (such as MS) and international experts. We
5 will recruit via targeted personal emails and will aim to get a balance of different professionals,
6 different condition expertise and national and international views. For professionals, our focus
7 will be to collect data on whether participants work as part of a fatigue service or not; their thoughts
8 and experiences of specific advice and interventions and their use of the fatigue research evidence.

9

10 **Phase 3: Development of fatigue management programme.**

11 In this phase, data and findings from key research literature (specifically from the most recent
12 reviews, that is, Aali et al, 2020; Hinkle et al, 2017) and from phases 1 and 2 of the study, will help
13 guide priority setting in the co-design of a new fatigue management programme. We will determine
14 what should constitute best practice for addressing PSF in the absence of research based clinical
15 recommendations in terms of the programme content, programme format, overall design and
16 presentation. Our co-design is informed by an Experience-based Co-design (EBCD) methodology
17 utilising the findings from earlier phases to trigger ideas and solutions for the new fatigue
18 management programme, and inform individual and joint priority setting (King's Fund, 2018). Ideas
19 on preliminary content and delivery will be explored through focus groups with stroke survivors,
20 carers, people with fatigue from other conditions and clinicians and further refined through staged
21 discussions with the study Patient and Public Involvement (PPI) group.

22

23 Using a co-design approach, we will aim to take an equitable approach to priority setting and
24 intervention design aiming for a balance and ratio of professionals, stroke survivors and carers. We
25 will also include those with experience of fatigue from other health conditions (e.g. multiple sclerosis,
26 rheumatoid arthritis) where the literature suggests the features of the presenting fatigue are similar
27 to those in stroke or where services seem to be addressing similar symptoms. We will be flexible,
28 depending on the data collected, as to how the groups are configured. We may also recruit some
29 number of participants from phase 2 to take part in these focus groups. These participants would be
30 selected on the basis that they had key experiences or novel ideas around fatigue management. The
31 overall aim is that the participants will have the opportunity to shape the programme and consider
32 how it might be best delivered.

33

34

35

1 **Informed consent**

2 In phase 1, completion and return of the questionnaires (either online or by post) will imply
3 informed consent to participate. Each questionnaire will have a front-page detailing information
4 about the study and contact details for obtaining further information. A separate information sheet
5 will also be provided.

6

7 In phases 2 and 3 all participants will provide informed consent. The researcher will explain the
8 details of the study and provide a participant information sheet, ensuring that the participant
9 has sufficient time to consider participating or not. The researcher will answer any questions that
10 the participant has concerning study participation.

11

12 No personal information will be collected until participants have given their consent. For patients
13 who are physically unable to sign the consent form (e.g. weakness in dominant hand due to stroke)
14 then consent will be given using a mark or line in the presence of an independent witness (who has
15 no involvement in the study) who will then corroborate by signing the consent form.

16

17 An accessible information sheet will be provided to those with aphasia. This follows standard
18 aphasia-friendly principles with one idea presented per page in short simple sentences in large font.
19 Key words are emboldened and each idea is represented by a pictorial image to support
20 understanding of what the study is about. The researcher will be trained to support understanding
21 further by reading parts of the information aloud and using supportive gestures/actions. Participants
22 who have used the accessible information provision will be provided with an aphasia-friendly
23 consent form and asked to initial all boxes before signing.

24

25 **Analysis**

26 Data from the survey will be analysed using SPSS and Excel using descriptive statistics. Free text data
27 will be analysed using broad categories and used to illustrate the quantitative data.

28

29 Qualitative interview and focus group data will be analysed separately, managed using NVivo
30 software, and use a framework approach (Gale, 2013). A working analytical framework will be
31 developed simultaneously and iteratively with the coding stage, and data chunks will be transferred
32 onto a framework matrix, which will also be informed by theory.

33

34

35

1 **Study Management**

2 The chief investigator will have overall responsibility for study management and will oversee all
3 study management. A study steering group, comprising the co-investigators and PPI members will
4 oversee the study.

5
6 **Discussion**

7
8 PSF can have significant consequences for stroke survivors and their recovery: it is not simply a
9 trivial, unimportant symptom. Despite recognition of the need to manage PSF appropriately, it is
10 accepted that the current evidence base around PSF and its management is weak which may be
11 because previous research has examined potential individual contributing factors rather than
12 focusing on the broader issues. However, given the complex, multi-factorial profile of PSF, a single
13 therapy approach for the management of PSF is unlikely to be appropriate. We therefore have
14 suggested that, given PSF is multi-faceted, it requires a comprehensive management programme.
15 Involving experts (that is, stroke survivors, carers, people with fatigue arising from other conditions
16 and clinicians working with those with PSF and with fatigue from other conditions) in the co-design
17 of such a programme is vital as they can share the strategies which they believe are successful, from
18 a concrete and informed perspective.

19
20 Using experts, that is, both patient and professional experts, in the programme development also
21 has additional benefits. Aside from offering legitimacy to the programme, including a range of
22 participants and a mixed methods design ensures that evidence is collected from several sources
23 and that key issues are triangulated. Moreover, having a programme that is co-designed provides
24 the best opportunity to develop a programme that is practicable, accessible, which people will
25 engage with and which can be sustained over the longer term. Such a programme also has the
26 added benefit that, in drawing on the experiences of experts, there is the potential to enable stroke
27 survivors to self-manage their own fatigue. If individuals have belief in their capability (self-efficacy)
28 to manage their own condition, this can have positive impacts.

29
30 The research is novel given the fact that it uses key stakeholders in the development of the
31 programme. It also uses a mixed methods design which incorporates survey, interview, focus group
32 and co-design methodologies in order to be able to draw data and findings together from a range of
33 credible sources. It also draws on both knowledge of PSF techniques as well as from non-stroke
34 fatigue sources. However, as with any proposed research study, there could be difficulties in

1 conducting the study. It is possible that there is not a satisfactory response to the survey which
2 would have implications for the generalisability of our results. It is also possible that the required
3 numbers of participants in the second phase are not achieved, or that we are not successful in
4 including a diverse range of participants. Both of these would limit the value of our results.

5
6 It is our intention that this research will lay the foundations for conducting a future definitive RCT to
7 test the efficacy of the programme and to determine whether stroke survivors could indeed self-
8 manage their fatigue. If management of PSF were possible, it would potentially reduce its impact
9 and the concomitant effects on recovery and quality of life. Although our proposed RCT will be
10 conducted in the UK, the results would be relevant worldwide as the issue of managing post-stroke
11 fatigue appropriately is a global issue, as reflected in current national and international clinical
12 guidelines and on the fatigue literature.

13 14 **Key findings**

- 15
16 • We will identify successful strategies to be used in developing a comprehensive fatigue
17 management programme
- 18 • This programme will need to be fully evaluated in future studies and trials.

19 20 **What the study has added**

21
22 This protocol details proposed research to develop a comprehensive programme to manage post-
23 stroke fatigue (PSF) using expert input from key stakeholders to shape the proposed intervention.

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