Development of a Questionnaire to Investigate Study Design Factors Influencing Participation in Gait Rehabilitation Research by People with Stroke: A Brief Report

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ABSTRACT

Purpose: The main objective of this study was to evaluate the feasibility of a newly developed questionnaire to assess the influence of study design on participation in gait rehabilitation research in a pilot test with individuals with stroke. A secondary objective was to investigate the relationship between participation in gait rehabilitation research and social and clinical factors of interest after stroke. **Methods:** A questionnaire was developed with expert opinion and guidance from related previous research. The questionnaire was pilot tested in a group of 21 people with stroke, and social and clinical factors (including gait function) were collected. Gait function was assessed using a pressure-sensitive mat; social and clinical characteristics were extracted from patient charts. Correlations were performed to investigate relationships between questionnaire responses and gait function, motor impairment, and chronicity; *t*-tests were used to examine response differences between people with a caregiver at home and those without. **Results:** A total of 21 people with stroke completed the questionnaire without difficulty; mean completion time was 7.2 (SD 3.5) minutes, with a range of responses across participants. Borderline significant associations were found between gait function and the number of studies in which a person would participate and between stroke chronicity and the location of studies in which a person would participate. **Conclusions:** A questionnaire to investigate the influence of study design factors on participation in rehabilitation research is feasible for administration in the post-stroke population and has potential to inform the design of future studies.

Key Words: gait; rehabilitation; research design; research participation; stroke; surveys.

RÉSUMÉ

Objectif : Le principal objectif de cette étude était de juger la faisabilité d'un nouveau questionnaire qui évalue l'influence des facteurs de conception d'une étude sur la participation à une recherche sur la rééducation de la démarche dans le cadre d'un essai pilote avec des personnes ayant subi un accident vasculaire cérébral (AVC). Un objectif secondaire consistait à réaliser une enquête sur le lien entre la participation à une recherche sur la rééducation de la démarche et les facteurs sociaux et cliniques d'intérêt après un AVC. **Méthodes :** Un questionnaire a été élaboré grâce à des avis d'expert et des recommandations provenant d'une recherche antérieure connexe. Le questionnaire a été mis à l'essai dans un groupe de 21 personnes ayant subi un AVC, et des facteurs sociaux et cliniques (y compris la capacité liée à la marche) ont été recueillis. La capacité liée à la marche a été évaluée à l'aide d'un tapis sensible à la pression; des caractéristiques sociales et cliniques ont été extraites des dossiers des patients. Des corrélations ont été effectuées pour mener une enquête sur les liens entre les réponses au questionnaire et la capacité liée à la marche, la déficience motrice et la chronicité; des tests *t* ont été utilisés pour examiner les différences entre les réponses des personnes ayant un fournisseur de soins à la maison et de celles qui n'en ont pas.

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Competing Interests: None declared.

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Résultats : Un total de 21 personnes ayant subi un AVC ont rempli le questionnaire sans difficulté; la durée moyenne pour le remplir était de 7,2 (ET de 3,5) minutes, et un éventail de réponses a été formulé par les participants. Il y avait des associations quasi importantes entre la capacité liée à la marche et le nombre d'études dans lesquelles une personne participerait et la chronicité liée à l'AVC et l'emplacement des études dans lesquelles une personne participerait. **Conclusions :** Il est possible de faire remplir un questionnaire à des personnes ayant subi un AVC afin d'étudier l'influence des facteurs de conception d'une étude sur la participation à la recherche en réadaptation; le questionnaire peut aussi éclairer la conception de futures recherches.

Research is critical both to evidence-based practice and to advancing physiotherapy.¹ One of the most difficult aspects of research is participant recruitment;² information about what factors influence participation can be used to guide study design in an effort to ensure efficient recruitment of participants who represent the population of interest.²⁻⁴

Stroke is the leading cause of adult neurological disability, and a need to investigate research participation by individuals with stroke has been identified.³ Participation in medical stroke studies is negatively affected by pre-existing unfavourable personal attitudes toward research and by external influences with a perceived stance against participation (e.g., family, religion, news media).⁵ People with stroke who participate in acute or secondary medical prevention research differ in social and clinical presentation from those who do not participate.³ For example, one study found that medical research participants had better function before their stroke and were more likely to be married than non-participants.³ Such findings raise concerns about the generalizability of medical research results to the general population of people with stroke.

Participation in rehabilitation research may be influenced by different factors than participation in medical research because of differences in the nature of participation.⁶ It is also possible that stroke rehabilitation research participants differ from non-participants and that study design factors (e.g., location of the study, number of sessions) may influence who participates and who does not.⁶ At present, however, little information exists about factors that influence participation in rehabilitation research.

An important first step to understanding participation in rehabilitation research after stroke is to develop a tool that can evaluate factors influencing participation. Our study focused on participation in gait rehabilitation research because of the importance of gait function to individuals post-stroke and the attention it receives during physiotherapy.^{7,8} Our primary objective was to pilot test a newly developed questionnaire to assess the influence of study design on participation in gait rehabilitation research after stroke. The secondary objective was to investigate the relationship between participation in such research and social and clinical factors of interest after stroke.

METHODS

Questionnaire development

Initial meeting

We (two neurorehabilitation physiotherapists with research experience and four senior MPT students) met face to face to discuss rehabilitation research participation, with the guiding hypothesis that the design of rehabilitation gait studies may influence participation by people with stroke. The primary objective of the meeting was to generate a list of study design factors that could influence research participation. This discussion was primarily informed by our expert opinion because we know of no previous work on research participation specifically related to study design.

A secondary objective was to generate a list of social and clinical factors that might be related to participation in gait rehabilitation research after stroke. This discussion was informed by some related literature on stroke research participation,⁵ but because this was a pilot study, we prioritized those factors of interest that could easily be collected via a chart review and an over-ground gait assessment. The final lists of factors were determined by consensus. The final list of study design factors consisted of study location, time commitment required of the participant, length of data collection session, presence of other participants, and effort required from the participant. The final list of social and clinical factors was presence of a caregiver, chronicity of stroke, motor impairment, and gait function. Because willingness to participate in a hypothetical study predicts actual participation,⁹ we decided to develop a questionnaire that would describe hypothetical gait rehabilitation studies and ask respondents to indicate whether or not they would participate in each study.

Initial draft of questionnaire

Through consensus, we created an initial draft of the questionnaire to assess the influence of study design on research participation. This draft described 12 hypothetical gait rehabilitation studies, and respondents were to indicate whether they would participate in them (yes or no). The hypothetical studies systematically varied in location (home vs. laboratory), time commitment (one session vs. multiple sessions), length of data collection session (1 h vs. 2.5 h), presence of other participants

(present vs. absent), and effort required from the participant (single vs. multiple measurements). Additional questionnaire items asked respondents to rate their understanding of their condition on an 11-point scale (0 = no understanding; 10 = complete understanding) and indicate in which season (spring, fall, winter, summer) they might participate.

The initial draft was shared with 12 volunteer reviewers with knowledge of stroke rehabilitation (physiotherapists and senior physiotherapy students), who independently reviewed the questionnaire and provided feedback on design and clarity.

Second draft of questionnaire

We revised the questionnaire's format and content on the basis of reviewers' feedback. A frequent comment was that the length, format, and number of hypothetical studies made the questionnaire difficult to follow and respond to; on the basis of this feedback, we shortened the questionnaire to focus on study design factors believed to be most important (the factor "presence of other participants" was dropped); reformatted it into a table for ease of reading and responding; and added a free-form answer section to describe factors not identified on the questionnaire. We also reviewed a related acute stroke medical study⁵ and used its findings to inform our revisions. Questions to address two additional factors, financial compensation and previous experience with research, were included in the second draft. The questionnaire asked respondents to indicate whether compensation would affect their decision to participate (yes or no), whether they had previous experience with research (yes or no), and to rate that experience (0 = negative, 10 = positive). The final version of the questionnaire appears in the online Appendix.

Questionnaire pilot testing

Participants

The questionnaire was evaluated in a pilot test by 21 people with stroke. Participants with stroke were recruited from a private rehabilitation clinic and two rehabilitation hospitals. Because participants from the hospitals were recruited from either the outpatient department or the in-patient department just before discharge, their discharge destination was known. The inclusion criterion was history of stroke (no limit on time since onset); exclusion criteria were inability to understand written or spoken English and inability to communicate one-word answers to close-ended questions. The study was approved by the Western University and University Health Network Research Ethics Boards. All participants provided written informed consent.

Questionnaire administration and testing procedures

Participants completed the questionnaire independently but in the presence of a study investigator. We were interested in the feasibility of questionnaire admin-

istration, specifically whether the questionnaire (1) could be completed with minimal explanation or clarification from investigators, (2) could be completed within 20 minutes, and (3) returned a range of responses. Participants were encouraged to ask questions at any point during this interaction, and the study investigator made note of these questions and recorded the time to complete the questionnaire, including the questions and answers related to its completion.

Testing procedures for social and clinical factors

Gait function was characterized by preferred-pace, over-ground gait velocity,^{10,11} assessed with a pressure-sensitive mat (GaitRite Mat, CIR Systems, Sparta, NJ). Social and clinical factors of interest were extracted from patient charts: date of stroke, presence or absence of a caregiver, and a valid and reliable measure of leg and foot motor impairment, the Chedoke-McMaster Stroke Assessment (CMSA).¹²

Data and statistical analysis

All statistical analyses were performed with SAS version 9.3 software (SAS Institute, Inc., Cary, NC). The total number of yes responses (maximum = 8) was summed for each participant; in addition, yes responses were summed for the hypothetical studies, grouped in the following categories: (1) studies at home (Studies 1–4), (2) studies in a lab (Studies 5–8), (3) studies with low time commitment (Studies 1, 2, 5, and 6), (4) studies with high time commitment (Studies 3, 4, 7, and 8), (5) studies with low required effort (Studies 1, 3, 5, and 7), and (6) studies with high required effort (Studies 2, 4, 6, and 8).

To address the secondary objective, we used Pearson correlation coefficients to investigate the relationship between research participation (total yes responses and yes responses to each study category) and social and clinical factors of interest (time since stroke, gait velocity, CMSA score). We used unpaired *t*-tests to compare responses of those with and without a caregiver.

RESULTS

Pilot test of questionnaire

Participants

A total of 21 participants completed the questionnaire in a mean time of 7.2 (SD 3.5) minutes. The mean age of the group was 57.0 (SD 10.5) years, and mean time since stroke was 166.5 (SD 289.9) days. Eleven participants were female, and 6 participants did not have a spouse or person at home to act as a caregiver. The mean leg and foot scores on the CMSA were 5.7 (SD 0.9) and 5.3 (SD 1.0), respectively, and the mean gait velocity was 85.2 (SD 27.5) cm/s.

Questionnaire administration and responses

All participants reported that the questionnaire was easy to understand and complete. The most common

Table 1 Questionnaire Responses

Study parameters	Hypothetical gait rehabilitation study								Total yes
	Study 1	Study 2	Study 3	Study 4	Study 5	Study 6	Study 7	Study 8	
Location	Home	Home	Home	Home	Lab	Lab	Lab	Lab	
Time commitment	Low	High	High	Low	Low	High	High		
Level of effort	Low	High	Low	High	Low	High	Low	High	
ID and velocity (cm/s)									
S1: 57.4	Yes	Yes	Yes	Yes	Yes	Yes	No	No	6
S2: 21.3	No	No	No	No	No	No	No	No	0
S3: 70.9	Yes	No	Yes	No	No	No	No	No	2
S4: 80.8	Yes	No	Yes	No	Yes	No	Yes	No	4
S5: 95.7	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	8
S6: 63.7	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	8
S7: 81.5	No	No	No	No	Yes	Yes	Yes	Yes	4
S8: 135.1	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	8
S9: 92.9	No	No	No	No	No	No	No	No	0
S10: 82.1	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	8
S11: 85.1	Yes	Yes	No	No	Yes	Yes	No	No	4
S12: 64.3	Yes	Yes	Yes	Yes	Yes	No	Yes	No	6
S13: 107.3	Yes	Yes	No	No	No	No	No	No	2
S14: 101	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	8
S15: missing	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	8
S16: 104.1	Yes	No	Yes	No	Yes	No	No	No	3
S17: 102.6	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Missing	7
S18: 123.5	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	8
S19: 77	No	No	No	No	No	No	No	No	0
S20: 115.2	Yes	Yes	Yes	No	Yes	Yes	Yes	No	6
S21: 41.6	Yes	No	No	No	Yes	No	No	No	2
Total yes	17	13	14	10	16	12	12	8	

Included are gait velocity and yes–no responses to the eight hypothetical gait rehabilitation studies for each participant.

clarification we made was to instruct participants to assume they were eligible to participate in all the hypothetical studies described.

There was a range of yes or no responses to the hypothetical studies across participants (see Table 1); the mean number of total yes responses was 4.9 (SD 3.0). The mean rating for “understanding of your condition” was 8.8 (SD 1.3). Twelve participants indicated that financial compensation would affect their decision to participate, but the question did not specify whether the effect would be positive or negative. Spring, summer, and fall were identified about equally as seasons in which respondents would participate (by 13, 16, and 14 participants, respectively); winter was less popular (4 participants). Three participants had previously been invited to participate in research; 1 (Participant 7) had agreed to participate and rated this experience as 0 (extremely negative). Ten participants completed the free-form section of the questionnaire, which asked about other factors that might affect their decision to participate. Additional factors identified in the free-form section could be classified as either personal or study related. The personal factor most commonly identified as affecting participation was work ($n = 2$); the two most commonly identified study-related factors were

benefits of the study to self or others ($n = 3$) and how the researchers explained the study ($n = 3$).

Relationship between rehabilitation research participation and social and clinical factors

We found borderline significant positive associations between gait velocity and total number of yes responses ($r = 0.44$, $p = 0.05$) and a borderline significant negative association between time since stroke and yes responses to lab studies ($r = -0.43$, $p = 0.05$). We found no significant relationships between yes responses and CMSA leg ($r = 0.28$, $p = 0.31$) or foot scores ($r = 0.22$, $p = 0.43$) and no significant differences between respondents with a caregiver at home and those without ($p = 0.16$).

DISCUSSION

This brief report presents preliminary results from a questionnaire developed to investigate study design factors that influence participation in post-stroke gait rehabilitation studies. On the basis of average completion time and the minimal level of clarification required by participants, we conclude that the questionnaire is easily understood by English speakers without communication impairments, can be completed in a reasonable amount of time, and returns a range of responses across participants.

To the best of our knowledge, this is the first study to specifically examine the influence of study design on participation in post-stroke rehabilitation research and its relationship with social and clinical factors. Previous work on participation in medical intervention research for stroke involved either retrospective analysis of participants and non-participants across various hospital-based medical studies or a questionnaire-based approach that focused on factors influencing participation in a single medical study.^{3,5,13} Thus, previous work did not take into account the multiple study design factors considered in our pilot study.

Our findings reveal a trend toward a positive relationship between mobility (walking speed) and willingness to participate in rehabilitation research after stroke, consistent with previous research findings that people with stroke who had better premorbid function were more likely to participate in hospital-based medical research.³ We also found a trend toward a negative relationship between chronicity of stroke and willingness to participate in lab-based studies. Interestingly, in our study the presence of another individual at home who could act as a caregiver did not appear to influence willingness to participate in rehabilitation research; a previous study found that medical research participation was more likely in people with stroke who were married.³ Pre-existing negative attitudes about research have been shown to adversely influence participation in medical stroke research,⁵ but because only one participant in our sample reported prior research experience, our findings cannot support or refute that association.

Our study has several limitations. First, there is a possibility of bias in our methods, because people who agreed to complete the questionnaire may also have been more likely to answer yes to participation in any of the hypothetical studies. However, Participants 2 and 19 responded no to all the hypothetical studies, which suggests that this is not the case. A second limitation of our study is the restricted assessment of social and clinical factors that potentially influence research participation. There is conflicting evidence about the role that education and socio-economic status play in medical research participation by people with stroke; some studies have found an influence,³ and others have not.^{5,13} Future work will need to examine in greater detail the impact of the interaction between social and clinical factors (e.g., socio-economic status and cognition) and study design on rehabilitation research participation after stroke. Future work should also include further validation and reliability testing in a larger group of individuals with stroke. Finally, we do not have detailed information

about the volunteer reviewers who provided feedback on the initial questionnaire draft.

The questionnaire described here has the potential to inform the design of future gait rehabilitation studies to facilitate recruitment of participants who better represent the general stroke population. Furthermore, by appropriately adapting the hypothetical study descriptions, the questionnaire could also be used to inform other fields of rehabilitation research such as upper limb stroke rehabilitation.

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