Understanding factors contributing to participant satisfaction in stroke walking recovery clinical trials

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Stroke \hfill \textbf{Background:} Individuals with stroke face a distinct set of challenges, barriers and facilitators that need to be understood to streamline efficacy of stroke clinical trials and improve participant retention. Few long-term stroke rehabilitation trials have evaluated participant perception of their laboratory experience.

\textbf{Methods:} We collected data regarding trial satisfaction from 33 individuals with stroke who participated in 12 sessions of treadmill training which included pre, post and follow-up non-invasive brain stimulation and clinical assessments. We evaluated factors such as overall trial satisfaction, burden of testing, perceived benefits, perceived barriers, and perceived support using a participant satisfaction questionnaire (PSQ) that assessed participants’ overall trial experience.

\textbf{Results:} 97\% of our participants found participating in the study to be rewarding and would recommend it to others with stroke. Transcranial magnetic stimulation (TMS) testing was found to be the major perceived burden of participation while travelling to the lab was found to be the major perceived barrier to participation. Significant correlations were found between various items of the PSQ and clinical assessments.

\textbf{Conclusions:} This study helped us get a preliminary perspective into the benefits and barriers faced by persons with stroke enrolled in a 4-week long clinical trial. We observed that participant satisfaction was driven by various factors including functional status, personal relevance to the research, perceptive physical and mental health improvements, interaction with research personnel, and ease of testing protocols.

\section*{1. Introduction}

Majority of stroke clinical trials aiming to establish efficacy of new treatments use the randomized control trial (RCT) design, which is considered the gold standard for experimental research. RCTs typically focus on quantitative measurements to demonstrate intervention-based change, however, little information is available on participant satisfaction of the experimental process, intervention itself, or perceived barriers and facilitators during the study.

Understanding and reducing barriers to participation will enable successful recruitment and retention in human research studies. Participant satisfaction during a research study is shaped by various experiences throughout the entire process, starting from recruitment, informed consent, medical/eligibility screenings, safety questionnaires, assessments during the study, follow up visits, and finally the intervention itself. Previous non-stroke studies looking into attitudes towards participation in clinical trials have identified altruism, personal relevance, socialization, receiving health education, and benefits from the study to be major contributing factors to participant experience\cite{1,2}. In addition, professionalism and respectful attitude displayed by the research team, participant’s access to privacy in the lab or clinic, and relationship built with lab personnel can also be important factors for a positive participant experience\cite{1,2}. Trial satisfaction is also influenced by study design including location of the study, duration of each session, number of sessions, and duration of the study itself\cite{3}. Recent studies have elaborated that personal benefits and a streamlined trial design are becoming main drivers of trial satisfaction along with a detailed explanation of the study and importance of randomization during the consent stage which is key for managing participant expectations\cite{2,4,5}. Participant’s prior expectations, attitude towards experimental studies, and understanding of the risks and benefits of the study play a further role in compliance and satisfaction\cite{6,7}. Several factors contribute to burden of participation including lengthy questionnaires regarding medical history, medley of clinical testing,

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physiological/biomechanical/neurological testing, long term training sessions, and follow-up visits [8,9]. Although participants are provided some form of financial support for research participation, frequent extended visits create a significant physical, financial, and psychological burden on participants and their caregivers [10–12].

The above-mentioned studies provide valuable information regarding participant trial satisfaction and burden, however most of these studies have been performed in populations other than stroke.

Individuals with stroke face a distinct set of challenges and may have different barriers and facilitators that need to be better understood to increase efficiency of stroke clinical trials. For example, most post-stroke training studies are longitudinal and include motor or cognitive interventions (such as gait training, upper extremity functional training etc.) which involve long study sessions, multiple laboratory visits and extended study protocols for follow-up testing. Participants may spend a lot of time and effort participating in a clinical trial with little physical or financial benefit. In addition, stroke neurorehabilitation studies may utilize supplementary neurophysiological tools such as non-invasive transcranial magnetic brain stimulation (TMS), a common research tool used to study the human brain but can be quite arduous to experience [13]. No previous study has explored participant perception of TMS in longitudinal stroke studies.

As a first step, we examine trial satisfaction of individuals with stroke who participated in a long-term gait training study which included non-invasive brain stimulation and comprehensive clinical walking assessments. We also explored if biometric variables such as age, race, gender, disease stage, impairment level, and dominance influence overall trial experience.

2. Methods

2.1. Overview of the gait training study

We retrospectively analyzed data obtained from a custom questionnaire developed to evaluate participant satisfaction collected as a part of a larger randomized clinical trial (Clinical trial registration: NCT03492229) in the Brain Plasticity Lab at the University of Illinois at Chicago, IL. Results of the main study have been reported elsewhere [14]. In brief, the study consisted of participants undergoing high-intensity speed-based treadmill training (HISTT) combined with motor priming (non-invasive transcranial direct current stimulation (tDCS) or sham stimulation with or without an ankle motor task) for 1 hour per day, 3 times a week for 4 weeks. Main outcome measures included clinical tests of walking function, and corticomotor excitability measured using TMS.

2.2. Participants

Thirty-three individuals with chronic stroke (23 males and 10 females, mean age 59 ± 9 years) who participated in the last two years of the RCT completed the questionnaire. Inclusion criteria for the RCT included individuals who were diagnosed with a single, unilateral stroke (>6 months from onset), age between 50 and 80 years, who exhibited residual gait deficits and were able to walk without an ankle orthosis for 5 min at a comfortable pace. Individuals with contraindications to brain stimulation such as presence of metal implants in the brain, history of seizures, medications that alter central nervous system excitability, history of skull fracture and/or concussion were excluded from the study. Participants with brainstem/cerebellar lesions, cognitive impairments, severe osteoporosis, contractures in the lower limb, cardio-respiratory or metabolic disorders or any infectious disease were also excluded. Each participant provided a written, signed informed consent form and were provided the opportunity to ask any questions during and after the consent process. Participants were reassured of their right to withdraw from the study at any time and the investigators asked specific questions about the study to assess whether the participant understood the involved procedures. Participants were provided a copy of the informed consent so they could reference any information or contact details. After the signing of the informed consent form, a detailed medical history questionnaire was obtained during the in-person screening session, in addition to initial assessments of walking speed and cognitive impairment using the 10-meter walk test and Mini-Mental State Examination (MMSE), respectively.

2.3. Intervention

Eligible participants underwent 36 sessions of HISTT (with or without priming). Participants were randomly assigned to one of the four intervention arms dictating the priming received prior to HISTT: 1) control – 15 min of rest, 2) tDCS – 15 min of 1 mA of facilitatory anodal tDCS only, 3) Ankle Motor Tracking (AMT) – participants completed a skilled visuomotor target tracking task with their paretic ankle combined with sham tDCS for 15 min, and 4) tDCS + AMT – 15 min of concurrent priming with 1 mA of facilitatory anodal tDCS and AMT. tDCS is a safe non-invasive neuromodulatory tool that delivers low intensity direct currents to the scalp and has been used extensively in research with minimal side effects reported [15]. Participants typically report none to mild discomfort with tDCS. The 40 min of treadmill walking included: 5-min warm-up, 30-min high-intensity speed-based intervals interleaved with active recovery, and a 5-min cool down. Speed based intervals involved participants walking at 50% of their maximal overground speed on the treadmill for 2 min. If the participant could safely maintain the peak speed achieved during an interval, treadmill speed was increased by 10% for the subsequent interval. If a participant displayed signs of instability or had an excessive increase in heart rate during an interval, peak speed was decreased by 10% for the subsequent interval.

2.3.3. Outcome measures

Clinical and neurophysiological outcomes were collected at baseline, at the end of 4 weeks of training, and at 3-months following completion of study. Clinical testing and TMS sessions were conducted on separate days with each session lasting approximately two to three hours. Participants completed the trial satisfaction questionnaire after completion of training.

2.4. Clinical tests

We performed the following standardized clinical tests of function: 10-meter walk test (10MWT), Mini-BESTest, Berg Balance Scale (BBS), 6-minute walk test (6MWT), Fugl-Meyer Lower Extremity (FMLE) assessment, Stroke Impact Scale, Activities – Specific Balance Confidence Scale, and EuroQol-5D. Please refer to the Supplemental Materials for a detailed description of each test.

2.5. Neurophysiological assessment

Transcranial Magnetic Stimulation (TMS): TMS is a non-invasive
method of brain stimulation used in research to assess functional connectivity of muscle representations within the motor cortex. We used single-pulse TMS delivered via a 110 mm double-cone coil connected to a Magstim 200 stimulator (Magstim, Dyfed, Wales, UK) and recorded EMG responses from the bilateral tibialis anterior (TA) muscle during 10% maximum voluntary contraction [14]. Recruitment curves were generated by applying stimulation at seven intensities (6 stimuli at each of 80, 90, 100, 110, 120, 130, and 140% of active motor threshold). Average stimulation intensity for the non-paretic TA was ~44% maximum stimulator output and for paretic TA was ~51% maximum stimulator output.

2.6. Participant satisfaction questionnaire (PSQ)

Participants completed the PSQ at the end of their 4-week training after clinical and TMS assessments had been conducted. The PSQ was adapted from a previous study by Courneya et al. (2013). We incorporated the same five domains used in this study with adjustments of sub-domain questions to address the stroke population more specifically [16]. The PSQ assessed five main domains: 1.) Overall trial satisfaction, 2.) Burden of testing, 3.) Perceived benefits, 4.) Perceived barriers and 5.) Perceived support. Each domain had sub-items ranging from 3 to 11 items (described below) which asked participants to rate their answers on a scale from 1 to 5; -1 corresponding to ‘not at all’, 2 to ‘to a small extent’, 3 to ‘to some extent’, 4 to ‘to a moderate extent’, and 5 corresponding to ‘to a large extent’.

The Overall trial satisfaction domain evaluated participants on benefits they perceived by participating in the study. This was assessed through 5 items: rewarding, waste of time, useful for research/helping others, useful for me personally, and recommend to other stroke survivors.

The Burden of testing domain evaluated participants on how much of a burden trial assessments were for them. Assessments included Transcranial Magnetic Stimulation (TMS), clinical tests, and questionnaires.

The Perceived benefit domain evaluated participants on perceived effects the intervention had on their quality of life, physical fitness, fatigue, happiness, quality of sleep, depressed feelings, anxious feelings, stress, body weight/shape, illness/injury, and appetite.

The Perceived barriers domain evaluated participants on how much of a barrier each of the factors were during their training program. Factors listed were feeling tired/fatigued, side effects of stroke, side effects of treatments, other medical/health problems, too busy/limited time, pain/soreness, lack of motivation, and travelling to lab.

The Perceived support domain assessed participants on how much support they received from each of the individuals listed during their training program. The individuals listed were spouse/partner (if applicable), other family members, friends, neurologist, and lab personnel.

2.7. Statistical analyses

Statistical analyses were performed using SAS software 9.4 (SAS Institute Inc., Cary NC) with significance level set at p ≤ 0.05. Descriptive tests were performed on all variables. Normality of all variables was examined using the Shapiro-Wilk’s tests of normality. None of the variables were normally distributed except for age, hence we decided to use non-parametric tests for all analyses. Spearman’s rho correlation analyses were conducted to examine the relationship between variables from the post-training clinical tests (10MWT, Mini-BESTest, BBS, 6MWT, FMLE), participant demographic characteristics (age, gender, dominance, time since stroke, and race), and the five domains of the PSQ to further understand factors that influence participant satisfaction. Strength of the correlation coefficient was classified as zero (0), weak (±0.1 to ±0.3), moderate (±0.3 to ±0.6), strong (±0.6 to ±0.9), and perfect (±1) [17].

3. Results

We included data from 33 participants who completed the PSQ. All 33 participants completed the entire study without any adverse events. Overall, 64% of participants were aged above 59 years, 70% were males, 52% were Black, 64% had hemiparesis on the left side of the body, and 82% were right dominant. Detailed demographic data are presented in Table 1.

3.1. Participant satisfaction questionnaire

Descriptive data for all questionnaire variables is provided in Table 2. For the Overall trial satisfaction domain, 97% of our participants reported that participating in the study was rewarding and that they would recommend it to other persons with stroke. Participation in TMS testing was reported to be the most burdensome with an average score of 2.19 out of 5 (0-lowest satisfaction, 5-highest satisfaction). Participants noted that the intervention-based training program improved their physical fitness (4.37), happiness (3.88), quality of sleep (3.42) and quality of life (3.97). Travelling to the lab (1.76) and overall fatigue (1.73) were identified as the biggest barriers to successful participation in the study. Lab personnel (4.29) and spouse/partner (3.83) were perceived to be of major support for participation.

3.2. Correlations

FMLE motor non-paretic side showed a significant moderate positive linear correlation with physical fitness (rho = 0.372, P = 0.033), personal usefulness (rho = 0.349, P = 0.047), and lack of motivation (rho = 0.366, P = 0.036). Age exhibited a significant moderate positive linear correlation with fatigue (rho = 0.381, P = 0.029) and support from other family members (rho = 0.445, P = 0.009). A significant moderate negative linear correlation was observed between time since stroke and clinical testing burden (rho = −0.395, P = 0.023), 10MWT self-selected speed and travelling to the lab (rho = −0.389, P = 0.025), the Mini-BESTest and fatigue (rho = −0.377, P = 0.031), 6MWT and travelling to the lab (rho = −0.412, P = 0.017), FMLE non-paretic side and travelling to the lab (rho = −0.420, P = 0.015), time since stroke and symptoms and side effects of treatment (rho = −0.427, P = 0.013), and time since stroke and support from a spouse or partner (rho = −0.391, P = 0.024). All other correlations between descriptive variables, clinical tests, and PSQ items were not significant. All significant correlation

| Table 1 | Participant characteristics. |
|---------|-------------------------------|
| Demographics, stroke (n = 33) | Mean (SD) |
| Age (years) | 59.90 (9.57) |
| Gender: | |
| male | 23 |
| female | 10 |
| Time since stroke (years) | 6.16 (4.82) |
| Race (%): | |
| Black | 52 |
| White | 39 |
| Hispanic | 6 |
| Asian | 3 |
| Side affected: | |
| Right | 12 |
| Left | 21 |
| Dominance: | |
| right | 27 |
| left | 6 |
| 10MWT SS (meters/second) | 0.79 (0.23) |
| Mini-BESTest (/28) | 18.36 (4.19) |
| BBS (/56) | 49.36 (4.69) |
| 6MWD (meters) | 293.42 (92.94) |
| FMLE-M Paretic (/34) | 20.7 (4.28) |
| FMLE-M Non-Paretic (/34) | 28.67 (1.69) |
helping other stroke survivors. Nearly half of the sample population study to be personally useful, worth their time, and useful for research other stroke survivors (97%). Over 77% of our participants found the baseline function influences participant perception. Nearly all our participants found our study to be rewarding and would recommend it to logical assessments. We also determined if demographic variables and participants found in a randomized controlled study involving gait training, non-invasive brain stimulation, clinical and neurophysiological assessments. We also determined if demographic variables and baseline function influences participant perception. Nearly all our participants found our study to be rewarding and would recommend it to other stroke survivors (97%). Over 77% of our participants found the study to be personally useful, worth their time, and useful for research helping other stroke survivors. Nearly half of the sample population values are provided in Table 3.

4. Discussion

In this study, we present data for trial satisfaction from 33 stroke survivors who participated in a randomized controlled study involving gait training, non-invasive brain stimulation, clinical and neurophysiological assessments. We also determined if demographic variables and baseline function influences participant perception. Nearly all our participants found our study to be rewarding and would recommend it to other stroke survivors (97%). Over 77% of our participants found the study to be personally useful, worth their time, and useful for research helping other stroke survivors. Nearly half of the sample population (44%) found TMS testing to be a significant burden for them. 80% of participants reported that the intervention had a positive effect on their happiness, physical fitness, and quality of life. Travelling to the lab appeared to be the largest and most common barrier to participating in the RCT. Participants depended mostly on support from family and lab personnel for successful participation in the study.

4.1. Overall trial satisfaction

Similar to previous studies, we found that research making a meaningful contribution in their lives to be an important factor for overall trial satisfaction [12]. Detailed explanation of the study, study design, and gait training also played a significant role in participant satisfaction levels as they were well informed of trial expectations. We also explained our various safety measures which included using a safety harness, monitoring heart rate and blood pressure, and providing adequate rest breaks as applicable. Study design also contributed to high participant satisfaction levels. TMS sessions, clinical testing, and individual training sessions were scheduled on separate days, thus participants were never in the lab for more than 3 hours at a time to limit fatigue. Individual training sessions were structured considering participant availability and schedule leading to higher adherence and consistency. All aspects of the training were conducted in the same room minimizing participant burden to travel to different locations. Interestingly, we noted a positive correlation between FMLE scores of the non-paretic limb and personal usefulness indicating participants with less than normal function in their non-paretic side perceived the research to be more useful. The non-paretic lower limb was not truly “unaffected” reflected by the range of scores from 26 to 31 for a maximum score of 34. This finding of incomplete function in the unaffected side is supported by several upper limb studies [18–21] and one lower limb study [22]. We found this to be a surprising finding because not having full function or mild impairment of the non-paretic side significantly influences a participant’s perspective of research.

4.2. Burden of testing

About 44% of participants found TMS testing to be a significant burden for them. This is not surprising as TMS procedures can be cumbersome and time consuming with participants being seated for hours undergoing uncomfortable stimulations on the head along with muscle twitching, fatigue, and hearing loud clicking noises upon stimulation delivery. To make TMS sessions a more pleasant or rather less burdensome experience, one can use strategies such as increasing between-session breaks, introducing engaging tasks to tackle TMS related fatigue, and spending time educating participants on TMS to reduce any TMS-related anxiety which in turn will help improve overall participant satisfaction [23]. Clinical testing was found to be a significant burden for participation as well. Our results particularly showed that those with greater time after stroke found clinical assessments to be less burdensome probably because individuals with chronic stroke are better adjusted to the challenges of stroke in their personal and social lives, compared to those with newer strokes who are still navigating day to day activities with reduced function [24]. Persons with chronic stroke may also have a better understanding of potential benefits to participating in research and thus are more compliant to TMS, clinical tests, and questionnaire protocols [24].

4.3. Perceived benefits

Participants found the study to have a positive effect on various aspects of their life as shown by the high scores on the Perceived benefits domain of the PSQ. 79% of study participants felt the training program had a positive effect on their quality of life while 78% felt it had a positive effect on their happiness. The data also showed that participants who felt the training program had a positive effect on their physical

### Table 2

| Questionnaire                        | Average (SD) |
|--------------------------------------|--------------|
| Overall Trial Satisfaction           |              |
| Rewarding                            | 4.82 (0.39)  |
| Waste of time                        | 1.16 (0.72)  |
| Useful for research/helping others   | 4.79 (0.42)  |
| Useful for me personally             | 4.76 (0.61)  |
| Recommend to other survivors         | 4.94 (0.24)  |
| Burden of testing                    |              |
| TMS                                  | 2.19 (1.51)  |
| Clinical Tests                       | 1.55 (1.28)  |
| Questionnaires                       | 1.67 (1.38)  |
| Perceived Benefits                   |              |
| Quality of life                      | 3.97 (1.03)  |
| Physical Fitness                     | 4.36 (0.78)  |
| Fatigue                              | 2.82 (1.4)   |
| Happiness                            | 3.89 (1.36)  |
| Quality of Sleep                     | 3.42 (1.46)  |
| Depressed Feelings                   | 1.55 (1.15)  |
| Anxious Feelings                     | 1.58 (1.23)  |
| Stress                               | 1.72 (1.22)  |
| Body Weight/Shape                    | 2.34 (1.43)  |
| Illness/Injury                       | 1.53 (1.22)  |
| Appetite                             | 2.24 (1.39)  |
| Perceived Barriers                   |              |
| Feeling tired/fatigued               | 1.73 (0.98)  |
| Side Effects of Stroke               | 1.64 (1.03)  |
| Side Effects of Treatments           | 1.27 (0.98)  |
| Other medical/health problems        | 1.27 (0.8)   |
| Too busy/limited time                | 1.27 (0.67)  |
| Pain/Soreness                        | 1.3 (0.81)   |
| Lack of Motivation                   | 1.13 (0.71)  |
| Travelling to Lab                    | 1.76 (1.17)  |
| Perceived Support                    |              |
| Spouse/Partner (if applicable)       | 3.83 (1.58)  |
| Other family members                 | 3.47 (1.63)  |
| Friends                              | 3.52 (1.53)  |
| Neurologist                          | 2.48 (1.76)  |
| Lab Personnel                        | 4.29 (1.49)  |

### Table 3

| Correlations                        | rho    | p-value |
|-------------------------------------|--------|---------|
| Positive correlations:              |        |         |
| FMLE-M Non-Paretic vs Physical fitness | 0.372 | 0.033   |
| FMLE-M Non-Paretic vs Lack of motivation | 0.366 | 0.036   |
| FMLE-M Non-Paretic vs Personal usefulness | 0.349 | 0.047   |
| Support from other family members vs Age | 0.445 | 0.009   |
| Fatigue vs Age                      | 0.381  | 0.029   |
| Negative correlations:              |        |         |
| Time since stroke vs Burden of clinical testing | -0.395 | 0.023   |
| 10MWT SS vs Travelling to lab       | -0.389 | 0.025   |
| MBT vs Fatigue                      | -0.377 | 0.031   |
| 6MWT vs Travelling to lab           | -0.412 | 0.017   |
| FMLE-M Non-Paretic vs Travelling to lab | -0.420 | 0.013   |
| Time since stroke vs Side effects of treatment | -0.427 | 0.013   |
| Time since stroke vs Spouse or partner support | -0.391 | 0.024   |
fitness had higher FMLE scores in their non-paretic leg. We also observed near significant correlations between the BBS and the PSQ variable quality of life, as well as clinical tests like the TUG, FMLE NP, FMLE P, and the PSQ variable appetite. Positive correlations between higher scores in clinical tests (indicating better function) and participants’ perception of the training program could be attributed to either higher functioning participants perceive better results with the training program, or these are participants who have had a stronger recovery arc in the recent years and are optimistic about the results they perceive from the program.

4.4. Perceived barriers

Travelling to the lab appeared to be the most common barrier to participating in the study, especially in those with slower walking speeds and more impairment in their non-paretic leg perceived. To reduce burden of travel, studies can provide compensation for travel (such as parking vouchers, tickets for public transportation or arrangement of private transportation). An easily accessible research location will also reduce this burden. Additional options could be remotely supervised interventions assessments to help alleviate this burden as participants can be involved in the study without leaving the comfort of their home [16]. We also found that those with lower balance indicated higher fatigue with the training program. This may be due to the increased energy expenditure seen in individuals with stroke, especially in those with lower function [25,26]. Factoring in rest breaks for those who need it more might be a strategy to improve efficacy of the intervention. Our results showed that people who had stroke for a longer time perceived side effects of treatments as less of a barrier to participation than individuals who have been diagnosed more recently.

4.5. Perceived support

Participants depended mostly on family and lab personnel for successful participation in the RCT. Support from lab personnel is critical for successful retention as participants value a professional and comfortable interaction with lab members [1,2]. Support from lab personnel can be provided by following simple rules of respectfulness, privacy, professionalism, efficient session organization, and making participants feel at ease and comfortable to interact and socialize in the laboratory environment [1,2]. Simple ways for lab personnel to provide a pleasant experience for participants includes offering them water or snacks during breaks, periodically checking how the participant is feeling throughout the session, as well as encouraging them vocally throughout the session to keep them motivated. Casual conversation can also create a warm and friendly environment. Over 75% of our participants said they received support from a spouse or life partner, however, this support diminished as time since stroke increased for participants. One reason for this may be the fact that 9 out of 33 participants responded ‘not applicable’ to this question perhaps because the more time that passes since a stroke, the higher odds for a spouse or life partner to no longer be around due to death, divorce, or other reasons.

4.6. Limitations

There are several limitations to our study. First, we only included people with chronic stroke, which may affect applicability of study results to an acute or subacute stroke population. We also had a small sample size of 33 participants out of our original sample size of 81. This was because we started collecting PSQ data only in the last two years of the study. All 33 participants completed the PSQ study, thereby these data do not accurately reflect barriers to participation from those who may not have completed the RCT (5 out of 81). Another possible limitation is that our PSQ results are specific to a long-term gait training study focusing on walking parameters and lower limb function. Different study protocols may yield different barriers to participation. For example, PSQ answers may be different for studies focusing on upper limb function, those involving a stationary set up, or those including an experimental drug. We also did not specifically ask about ‘burden of the intervention’ as a separate domain, as the intervention was covered in the Overall trial satisfaction and Perceived benefits domains. This may have provided us additional insight into participant perception of the intervention. Although we used a questionnaire that has been validated previously in another population, we are unable to compare and contrast the scores provided by our participants with other similar stroke clinical trials. It is also possible that the questionnaire we chose to assess trial satisfaction and perception did not completely capture participant experience. Rigorous qualitative data collections such as focus groups and interviews may offer more meaningful insights into participant beliefs and perspectives.

5. Conclusion

This study helped us get an in-depth first look into the perceived benefits and barriers faced by persons with stroke during participation in a 4-week randomized clinical trial that included treadmill training, and clinical and neurophysiological assessments. We observed that participant satisfaction is driven by various factors such as functional status, personal relevance to the research, perceptive physical and mental health improvements, as well as support and positive interaction with lab personnel throughout the course of the study. To improve patient retention and adherence, we suggest that future long term clinical trials focus on detailed explanation of the study, efficient study design to minimize participant burden, ease of travel for participants, ease of testing protocols, and positive interaction between participants and lab personnel.

Declaration of conflicting interests

The Authors declare that there is no conflict of interest.

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Table 1. Participant characteristics. Values are in Mean (Standard Deviation). 10MWT: 10 Meter Walk Test, BBS: Berg Balance Score, 6MWD: 6 Minute Walk test Distance covered, FMLE-M: Fugl-Meyer Lower Extremity Motor score.

Table 2. Average and standard deviations from 33 participants for the five domains of the Participant Satisfaction Questionnaire. Scaled values from 1 to 5 corresponding to the effect each domain had on participants’ overall experience -1 corresponding to ‘not at all’, 2 to ‘to a small extent’, 3 to ‘to some extent’, 4 to ‘to a moderate extent’, and 5 corresponding to ‘to a large extent’. TMS: Transcranial Magnetic Stimulation, SD: Standard Deviation.

Table 3. Statistically significant correlations between variables from clinical tests, participant demographics, and the five domains of the PSQ. Rho and p-values are provided for each significant correlation. Rho: Spearman’s rank correlation coefficient, FMLE-M: Fugl-Meyer Lower Extremity Motor score, 10MWT: 10 Meter Walk Test, MBT: Mini-BESTest, 6MWT: 6 Minute Walk Test.

Data availability

Data will be made available on request.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.conctc.2022.100945.

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