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Process evaluation findings of a fall prevention and management program for wheelchair and scooter users with multiple sclerosis

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ABSTRACT

Objective: To describe process evaluation findings of a clinical trial to evaluate the ***Individualized Reduction of Falls*** (iROLL) program, a 6-session, group-based intervention designed to reduce fall incidence among people living with multiple sclerosis (MS) who use a wheelchair or scooter full-time.
Methods: A mixed-methods process evaluation focusing on implementation and mechanisms of impact (MOI) was conducted. Both iROLL participants and trainers (licensed occupational or physical therapists) provided input.
Results: Seventeen iROLL participants and nine trainers participated. The overall session attendance rate was 93%. Content and logistics fidelity were 95% and 90%, respectively and average overall participant satisfaction rating was 4.7/5.0. Five MOI themes emerged: group dynamic, comprehensive nature of the program, strong program development, role of a skilled interventionist, and motivated participants. Recruitment challenged program reach.
Conclusion: iROLL is acceptable to the target audience, can be delivered with high fidelity and has diverse and interacting mechanisms of impact operating. Remote delivery may improve reach.
Innovation: Effective iROLL delivery requires trainers with strong group management skills who can also individualize material while maintaining program fidelity. Comprehensive training and on-going support of the occupational and physical therapists delivering iROLL bolsters program effectiveness. Program access may improve with online delivery.

1. Introduction

1.1. Falls among people with MS who use wheelchairs and/or scooters

Approximately 25% of people with multiple sclerosis (pwMS) are considered "non-ambulatory", defined as unable to perform a timed walk test [1], prompting wheelchair and/or scooter use to support mobility. Unfortunately, wheelchair and scooter use does not eliminate the risk of falls. Approximately 75% of pwMS who use a wheelchair or scooter full-time report at least one fall over a six-month period [2]. These falls typically occur during unavoidable day-to-day actions such as transferring, reaching, and walking short distances or standing [3] and can lead to serious injuries. In addition, 48% of the population report sustaining a physical injury as a result of a fall [2].

Falls, whether injurious or not, can lead to a cascade of sequala often driven by fear of falling. Approximately 75% of pwMS who use a wheelchair and scooter report a fear of falling, with 66% curtailing their activity as a result of these fears [2]. This fear of falling may adversely affect the quality of life and community participation in this population [4]. Although fall prevention research for this population is in its infancy, evidence points to interacting physical, behavioral and environmental contributors to falls [2,3,5-9] and the need for interventions that address these diverse influences on fall risk [10]. Findings from a single-group intervention study undertaken by Rice et al., (2018) [11] point to the promise of fall prevention for pwMS who use a wheelchair or scooter full time. In that study, a single, 45-minute educational session focused on improving the quality of transfer skills and seated postural control through practice opportunities and individualized instruction. Although no impact on fear of falling, quality of life or community participation was observed, fall frequency significantly decreased after exposure to the intervention [11].

1.2. Introduction to iROLL

Recognizing the potential of fall prevention interventions specifically designed for pwMS who use a wheelchair or scooter full-time, Rice, et al. conducted a multi-site, non-randomized trial to evaluate the efficacy of the *Individualized Reduction of FaLLs program* (iROLL). iROLL is an in-person, six-session, community-based, group intervention designed to

Abbreviations: MS, multiple sclerosis; MRC, Medical Research Council; MOI, Mechanisms of Impact; iROLL, Individualized Reduction of Falls Program.

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reduce fall incidence among pwMS who use wheelchairs or scooters, as well as improve functional mobility skills associated with fall risk (e.g., transfer and wheelchair skills, balance), increase knowledge of fall risk factors, decrease fear of falling, and enhance quality of life and community participation. The intervention is delivered by licensed physical or occupational therapists trained to implement iROLL [12].

iROLL is a complex intervention made up of multiple components and addresses a variety of influences on fall risk. The program has been previously described in Rice et al., (2019) [12]. Briefly, iROLL applies social learning theory [13], uses a self-management approach [14,15] and features brief didactic presentations, interactive group discussions, and numerous opportunities to practice both fall prevention skills (e.g., transfer techniques, therapeutic exercises) and self-management skills (e.g., goal setting and action planning). Learning is supported by videos and handouts informed by health literacy guidelines [16].

1.3. Role of process evaluations in complex interventions

As described by Moore et al. (2015), the Medical Research Council's (MRC) process evaluation framework emphasizes the relationship between three key areas of process evaluation: implementation, mechanisms of impact (MOI) and context. Implementation examines how delivery is achieved and what was actually delivered [17]. It includes fidelity, dose, adaptions (substantial changes made to the content or structure of the intervention), and reach (the proportion of the target population that participated). MOI examines how the intervention triggers change and the participants' response to the intervention [17,18]. Context examines how external factors (e.g., social, political or economic environments [19,20]) influence delivery, receipt, and outcomes of the program. Because process evaluations explore factors causing observed change (or lack thereof) they are essential to the design and testing of complex interventions [17,21,22]. Exploring unique factors that support fall prevention for this population is particularly salient given that "the most effective fall-prevention strategies for persons with MS have yet to be documented" [23].

1.4. Statement of purpose

This study reports the findings from an MRC-informed process evaluation conducted concurrently with the multi-site, non-randomized clinical trial undertaken to evaluate iROLL. The goals of the process evaluation were to: 1) examine iROLL's implementation, 2) examine iROLL's MOI, 3) examine strengths and limitations of the program, and 4) provide recommendations to strengthen the program for future use.

2. Methods

2.1. Study participants

The study was approved by the Human Research Protection Offices at the three study sites: The University of Illinois Champaign-Urbana (UIUC), University of Illinois Chicago (UIC), and the Shepherd Center (SC) in Atlanta, GA. All study participants provided written informed consent prior to engaging in any research activities.

Two groups of participants were included in this study: the licensed physical or occupational therapists who implemented iROLL (herein referred to as "trainers") and pwMS who use wheelchairs or scooters who participated in the iROLL intervention (herein referred to as "iROLL participants"). All iROLL participants were $\geq$18 years old with a self-reported diagnosis of MS whose main form of mobility is via a wheelchair or scooter. All reported needing minimal or moderate assistance to perform transfers or performed transfers independently and had experienced at least one fall in past 12 months [12]. iROLL participants were recruited via established research registries, including the North America Research Committee on Multiple Sclerosis (NARCOMS), flyers posted in areas frequented by pwMS, and presentations at MS support groups. A subset of the initial six participant groups were evaluated to examine the process of the intervention.

Strategies to recruit trainers varied by site. In (Atlanta, GA), a Co-Investigator invited occupational therapy and/or physical therapy clinical staff to participate. In (Chicago, IL), a Co-Investigator (EP) sent flyers to licensed, occupational therapy (University of Illinois Chicago) alumni. In (Champaign, IL), the study's Principal Investigator (PI) (LR) acted as the site's sole trainer and is a licensed, experienced physical therapist. Trainers who had at least two years of experience providing care to pwMS and engaged in at least one of six sessions in an iROLL cycle (i.e., 6 sessions completed for a given cohort) were invited to participate in the process evaluation. Initial trainer instruction was provided through an in-person workshop that had allotted six hours of training time, but the full time was not required. Ongoing meetings were held with the trainers periodically to answer specific questions regarding the implementation of the intervention. Similar to clinical practice, the trainers were encouraged to acknowledge the feelings and comments of participants and allow limited space to divergent conversation. Trainers were, however, encouraged to steer the conversation back to the topic at hand in order to assure all necessary items were covered during the session.

2.2. Process evaluation data collection

2.2.1. Data collected from iROLL participants

After each iROLL session, iROLL participants completed a post-session evaluation (*Participant Post Session Evaluation*) to collect information primarily pertaining to satisfaction with the session. After the final iROLL session, participants completed a post-course evaluation/feedback form (*Participant Final Course Evaluation Form*). Trainers stepped out of the room during post-session and post-course questionnaire administration. Participants completed questionnaires and then placed them in an envelope so that trainers could not see responses to offer anonymity. Also following the final iROLL session, participants engaged in a one-on-one telephone interview led by co-authors (JS, TV) which focused on MOI. Interviews were recorded and transcribed verbatim.

2.2.2. Data collected from iROLL trainers

After each iROLL session, trainers completed a fidelity checklist (*Trainer Fidelity Form*) to assess adherence to the session protocol. At the end of the course, all trainers completed a feedback form (*Post-Course Trainer Feedback Form*) to gain insight into program fidelity and MOI. Trainers were also invited to participate in a telephone interview with co-author (TV) to explore MOI. Questions focused on trainers' perspectives on participants' responses to the intervention and planned or unexpected mediating factors [17]. The PI was not interviewed due to her extensive involvement in iROLL's development. All trainer telephone interviews were recorded and transcribed verbatim. A full list of data collection strategies and associated forms can be found in Table 1. Developed study questionnaires were not pre-tested, but were based upon successfully used questionnaires in an earlier study [24].

2.2.3. Implementation data collection strategies

Fidelity was primarily assessed via the *Trainer Fidelity Form.* In addition, the iROLL *Post-Course Trainer Feedback Form* informed fidelity by exploring perceived adequacy of training, areas in which more/less time was needed in the iROLL program, session logistics, and quality of the participant and trainer manuals. Fidelity items were divided into: 1) Logistical fidelity, which examined the logistical aspects of the intervention (e.g., "I started on-time.") and 2) content fidelity, which examine the implementation of the intervention content. (e.g., "I provided an overview of the impact of MS symptoms on fall risk, …"). Fidelity was examined for each session.

Dosage was determined by calculating the duration of each iROLL session based on start and end times documented by trainers on Trainer Fidelity Forms. **Adaptations** were identified via documentation provided by trainers after each session**.** The PI (LR) and Co-Investigator (EP) discussed adaptations suggested by the trainers after each iROLL cycle to ascertain

Table 1
iROLL process evaluation data collection strategies.

Data source	Measurement area	Completed by	When completed
Trainer Fidelity Form	Implementation: Fidelity, Dose	Trainer	Post-session
iROLL Post-Course Trainer Feedback Form	Implementation: Fidelity	Trainer	Post-course
Adaptation log	Implementation: Adaptations	Trainer, Principal Investigator, Co-Investigator	Post-course
Study coordinator log	Implementation: Reach	Study coordinator	Completed on an ongoing basis during the study period.
Post-course, one-on-one trainer interview transcripts	Mechanism of Impact	Trainer	Post-course
Trainer Post-Course Feedback Forms	Mechanism of Impact	Trainer	Post-course
Post-course, one-on-one participant telephone interviews transcripts	Mechanism of Impact	iROLL participant	Post-course
Participant Post-Session Evaluations	Mechanism of Impact	iROLL participant	Post-session
Participant Final Course Evaluations Forms	Mechanism of Impact	iROLL participant	Post-course

impact on program fidelity. To attain insights into **reach**, each site's study coordinator monitored the number of calls to the research office by a potential participant with interest, the number of iROLL participants completing iROLL and the number declining to participate. Reasons for declining to participate were noted and attrition monitored. Any iROLL participants attending fewer than three intervention sessions were withdrawn from the study. Reasons for non-attendance were noted.

2.2.4. MOI data collection

The transcripts of the post-course, one-to-one trainer telephone interviews were the primary source of MOI data. Participant post-course, one-to-one telephone interviews, participant post-session evaluations, participant final course evaluation forms, and the trainer post-course feedback forms were also used to examine MOI.

2.3. Process evaluation data analysis

A descriptive analysis of the process evaluation data was conducted using Microsoft Excel (Redmond, WA). Close-ended questions were analyzed by examining responses based on a five-point Likert scale. For open-ended survey responses, data were reviewed, categorized and summarized by trained research assistants and discussed with the PI (LR) and Co-Investigator (EP). Qualitative interview data was explored using thematic analysis [25]. The initial analysis was conducted by two authors (TV, JS). Both had experience with qualitative analysis and were supervised by the PI (LR) and Co-Investigator (EP). After the initial themes were developed, all four authors (TV, EP, JS, LR) discussed the data until consensus on the final themes was reached.

The extent to which the trainers' views of MOI were supported by other data was examined by a member of the investigative team (TV) by comparing the findings from the one-on-one trainer interviews to findings that emerged from the transcripts of the telephone interviews conducted with iROLL participants, the participant post-session evaluations, the participant final course evaluation forms, and the iROLL post-course trainer feedback forms.

3. Results

3.1. Description of iROLL participants

Across the three study sites, the initial 17 participants who enrolled in the iROLL intervention contributed data to the process evaluation from March 2018 to April 2019. Table 2 outlines the key characteristics of the iROLL participants. Across the six iROLL intervention groups, the size ranged from two to three participants per group.

3.2. Description of iROLL trainers

Nine trainers, including the PI, completed the *Trainer Fidelity Forms* after each iROLL session and the iROLL *Post-Course Trainer Feedback Form* after completion of each iROLL cycle led. Eight trainers were invited to participate in the post-course, one-to-one interview. One trainer was unable to participate due to scheduling conflicts. Seven trainer interviews were conducted. Table 3 outlines the characteristics of the trainer data gathered for those participating in the post course, one-on-one trainer interviews. Trainer data was gathered between March 2018 and July 2019.

Table 2
Characteristics of the initial 17 iROLL participants who engaged in the process evaluation.

Variable	Value
Age (years) [mean SD], (range)	56.6 [10.8], (39 – 72)
Gender [n (%)]	Male = 3 (18) Female = 14 (82)
Types of MS [n (%)]	Relapsing-Remitting = 10 (59) Primary- Progressive = 1 (6) Secondary Progressive = 5 (29) Unknown = 1 (6)
Time with MS (years) [mean SD] (range)	18.8 [8.9], (8 – 38)
Years of wheelchair use, (years) [mean SD] (range)	10.4 [7.5], (1 – 32)
Type of wheeled mobility device [n (%)]	Power wheelchair = 13 (76) Manual wheelchair = 2 (12) Scooter = 2 (12)
Number of falls in the past 6 months, Median (Interquartile range)	2 (0.5–2)

3.3. Implementation findings

Table 4 provides a full summary of implementation findings, including a listing of strengths, limitations, and recommendations for future iterations of iROLL.

3.3.1. Fidelity findings

Findings from the *Trainer Fidelity Forms* indicated the intervention was delivered with 90.3% logistic fidelity and 95.2% content fidelity. Session 3 had the lowest overall fidelity rating at 89.6%. Table 5 summarizes fidelity scores based on the *Trainer Fidelity Forms*.

Table 3
Characteristics of the iROLL trainers participating in the post-course, one-on-one trainer interviews.

Variable	Value
Discipline [n (%)]	Occupational Therapists = 3 (43%) Physical Therapists = 4 (57%)
Experience range: [mean (range)]	8.5 years (2–16 years)
Report experience with working with people with MS [n (%)]	7 (100%)
Experience working with groups and previous research experience [n (%)]	6 (86%)
Self-reported training time by Trainers [mean]	2.71 hours

Table 4
Key results: summary of iROLL's strengths, limitations and recommendations.

Key strengths: implementation		Recommendations based on implementation strengths
Description of strength	Source (s)	
1. Adequacy of the training to prepare trainers to deliver iROLL was above average.	iROLL Post-Course Trainer Feedback Forms	1. Future trainings to prepare PTs and OTs to deliver iROLL should be modeled after the trainings utilized during the NMSS-funded effort. The amount of time (i.e., 2.71 hours) dedicated to the trainings, training processes, and content can be replicated in future trainings to prepare PTs and OTs to deliver iROLL.
2. iROLL was delivered with high fidelity.	Trainer Fidelity Forms	2. Future efforts to recruit iROLL trainers should replicate recruitment strategies utilized during the NMSS-funded project. These strategies included recruiting trainers through Co-Investigators' network and utilizing flyers emailed to associated university alumni. Trainers requirements included: ● Licensed PTs or OTs ● 2 years of experience, minimum ● 1 year of experience providing care to individuals with neurological impairments (ideally individuals with Multiple Sclerosis) utilizing wheeled mobility devices ● Experience providing education to patients/clients in a group setting Continue to invest in high quality training to prepare PTs and OTs to deliver iROLL (*Refer to recommendation 1 above.)* Continue to utilize the high quality manual to support intervention delivery *(Refer to recommendation 3 below)*.
3. The final version of the trainer manual was an effective resource supporting program fidelity. Note: Adaptations to the trainer manual were made after the 1st iROLL cycle. Key adaptations included: ● Consolidating the trainer protocol and trainer manual to create one trainer manual ● Adding page number references throughout to participant manual in trainer manual.	Personal communication with principal investigator and trainers, discussing positive/negative aspects of the program, including the manual. Email communication between first author and principal investigator	3. Future iROLL trainer manuals should retain features of the trainer manual used during the NMSS-funded study. NOTE: Trainers did not specify key features to retain for future use in data collected.

Key strengths: implementation		Recommendations based on implementation limitations
Description of limitation	Source (s)	
1. Trainers had difficulty managing time effectively during iROLL sessions.	iROLL Post-Course Trainer Feedback Forms Trainer telephone interview transcripts	1. Implement strategies to use time available during iROLL sessions as effectively as possible. For example: ● During training, educate the trainers who will be delivering the program about strategies to ensure that sessions on start time when participants arrive late. -For example: Trainers can be asked to consistently start sessions at the pre-determined start time. Consistent start times may help participants realize the importance of arriving on time. ● Build in a soft start to each session (which has been enacted per PI), meaning add 10 to 15 minutes at the beginning of each session for such things as review of key content from previous sessions and/or socialization. In the case of late arrival, this will minimize the missing of new content. ● Include dose recommendations per area in each session in both manuals ● Provide additional training to manage varied and multiple learning approaches utilized in each session. For example, trainers reported difficulty balancing and managing time related to robust group discussions and transfer training practice, especially in Session 3.
2. Trainers had challenges cross referencing between trainer and participant manuals	iROLL Post-Course Trainer Feedback Form	2. Enact the following trainer manual modifications: ● Provide trainer with access to both the trainer manual and the participant manual; ● Provide tabs in the trainer manual and in the participant manual to enhance usability - use tabs to separate sessions - use tabs to separate the trainer and the participant manuals within the trainer manual
3. Transportation was a significant challenge and concern for both participants and those deciding about participating in the intervention.	Study office call log Trainer telephone interview transcripts	3. Explore iROLL delivery options for all or portion of the intervention that support the highly valued group dynamic while increasing accessibility to the program. Options include: - Teleconference - Videoconferencing - Internet delivery for selected portions of the program - A hybrid delivery: Face to face to support overlearning and adequate technique with transfer and wheelchair (w/c) skills and one of the above delivery options for educational and group based processing/discussion.

Table 4 (*continued*)

Key strengths: implementation		Recommendations based on implementation limitations
Description of limitation	Source (s)	
4. Recruitment of iROLL participants took longer than expected and recruitment goals (to date) have not been met. Per communication with PI, recruitment goal as of May, 2019 was 60 participants enrolled.	Study office call log Email communication with principal investigator regarding recruitment goals	5. Explore alternatives to in-person iROLL delivery options for all or portion of the intervention (*Refer to recommendation 3 above*). Consider additional recruitment strategies or approaches, such as: ● neurologist ● wheelchair vendors ● additional MS Centers across the United States (U.S.) ● additional MS Walks across the U.S. Consider how to access/recruit those initially transitioning to a wheelchair (power and/or manual) and/or scooter.
5. Participants' access to a computer outside class was variable and this compromised participants' ability to fully engage available on-line material (e.g., exercise program examples) and recommended resources.	Trainer telephone interview transcripts iROLL Post-Course Trainer Feedback Forms	6. Create a loan program to make tablets or laptops available to participants. Loan program would need to include training to ensure participants are confident to use device.
6. Site specific implementation challenges: **Champaign and Chicago, IL sites**: Bathroom and classroom accessibility challenges reported by participants. **Atlanta, GA site**: Trainers experienced technical difficulties with the videos used in the iROLL program.	Trainer Fidelity Forms Post-course Trainer Feedback Forms iROLL Post-Course Trainer Feedback Forms	7. Site specific implementation recommendations: Explore site room accessibility in advance of an iROLL cycle. Specifically, consider: • Distance between participant parking area and building entrance • Distance between building entry and the room where the iROLL sessions are being held • Accessibility within the room to accommodate multiple wheelchair users • Select iROLL sites that make it possible to control room temperature, as participants requested a cooler room. • Having sufficient support personnel to assist participants with use of the rest room/navigating to the room as needed. Provide video backup options. For example: • Provide a PowerPoint-based handout at the back of both participant and trainer manuals. • During the iROLL trainer training, provide instruction to download videos on to a device in advance of an iROLL session to minimize the need to access the internet and bypass potential connectivity issues. • Provide each trainer with a study laptop or tablet. The content for the program could be fully downloaded and a notice to request the material not be downloaded to any other devices. The trainer could then return the laptop at the end of their service and minimize the risk of copyright infringement of the material.

Key strengths: MOI		Recommendations based on MOI strengths
Description of Strength	Source (s)	
1. Group dynamic	Trainer telephone interview transcripts Participant telephone interview transcripts	1. Continue to utilize a group format. Findings highlighted the value of the group, which provided a sense of comradery, a safe place to process and problem solve, and accountability to address shared action plans.
2. Comprehensive nature of the program	Trainer telephone interview transcripts Participant telephone interview transcripts	2. Continue to utilize a multi-factorial approach to fall prevention and management in future fall management programs for people living with MS who are full time wheelchair or scooter users. Retain features, content or components of value highlighted by iROLL participants, including: action planning, video materials, fall recovery plan, environmental safety, transfer training, exercise, awareness/knowledge about available resources, multiple sessions and wheelchair (w/c) set-up/maintenance. Retain features, content or components of value highlighted by iROLL trainers including: varied learning approaches, physical skill set development, hands on practice activities, supports safety awareness, supports decision making through choices, builds confidence throughout the program, supports exercise behavior change, provides resources, and assesses/problem solves falls and fall risk, and content supports various levels of ability and the potential progression of MS.
3. Strong program development	Trainer telephone interview transcripts	3. Continue to utilize an interdisciplinary team in all phases of the project. Continue to maintain the strong, current evidence base of the program's content and approach to fall management. Continue to use the integration of key themes throughout the program.
4. Role of a skilled interventionist	Trainer telephone interview transcripts Participant telephone interview transcripts	4. Continue to utilize experienced OTs and/or PTs as trainers. OTs and PTs are trained to have strong group management skills and be able to tailor and individualize treatment approaches as needed by client. Portions of iROLL (e.g., exercise modifications, finessing transfer technique) require this skill set. Both trainers and participants highlighted the valued group management skills, individualization and tailoring that trainers were able to provide during iROLL. As described above in the Implementation section (*Refer to point 1 in strengths*), future trainings to prepare PTs and OTs to deliver iROLL should be modeled after the trainings utilized during the NMSS-funded effort. A training addition could focus on the individualization and group management skills for trainers to continue to support strong program delivery.
5. Participant motivation	Trainer telephone interview transcripts Participant telephone interview transcripts	5. Request participants prior to or in Session 1 to share their motivation to participate in iROLL and document their responses. In iROLL, participant motivation supported participation and attendance. Reasons for participation included supporting MS research and gaining knowledge/skills to support fall prevention.

Key limitations: MOI		Recommendations based on moi limitations
Description of Limitation	Source(s)	
1. Trainers report an occasional lack of observed change in transfer or wheelchair skills, leading to questionable improvements to program outcomes.	Trainer telephone interview transcripts	1. Note: Per personal communication with the principal investigator, objective data indicates a significant improvement in transfer skills, but not in wheelchair skills at this point in the study. To support trainers' confidence in iROLL, provide an intermittent report/summary of selected data, particularly considering transfer and w/c skills, so they can see the measured progress of participants overall. Another option is to provide an end of the study report to iROLL trainers with the overall findings of the study, which may support trainer motivation to consider involvement in future iterations of iROLL.
2. Session 3 trainer fidelity ratings and participants' satisfaction ratings were the lowest of the 6 iROLL sessions.	Trainer Fidelity Forms Participant Session by Session Form Trainer telephone interview transcripts	2. Feedback regarding Session 3 was especially focused on the advanced transfer and w/c skills training. Review and revise Session 3 with specific attention to: ● Complex Power Wheelchair and Scooter Skills Education ● Complex Manual Wheelchair Skills Education Trainer prompts in both of the above sections reads: "Trainer Material: Please tell participants they will have a chance to practice now using the protocol outlined in the Transfer Protocol: Session 3." Consider adding trainer prompts following, which supports the value of practicing the skills. For example: "Reading and reviewing these skills are steps in the process to support safety and independence. To firm up one's ability to perform these skills safely and accurately, next up we need to practice these skills. Who would like to go first?" With respect to complex transfers, there are currently no prompts to the trainer to enact complex transfer practice. Current content includes video, lecture and group discussion. Consider adding a trainer manual prompt and build in 10 to 15 minutes to allow participants to practice complex transfer skills.
3. Exercises were too difficult for some participants, including a model that was advanced and seemed to have a spinal cord injury rather than MS.	Trainer telephone interview transcripts Participant telephone interviews iROLL Post-Course Trainer Feedback Forms	3. Provide examples of downgraded exercises in trainer manual. Provide these examples in a reference section in the back of the manual. (Note: Per PI, some of the more challenging exercises requiring a downgrade were available in both participant and trainer manuals). During the training to prepare trainers to deliver iROLL, emphasize the option of using downgraded exercises during iROLL sessions. For the video, consider hiring 2 people with MS to model the exercise program. • One person can model the "standard" exercise procedures; • The other person can model the less advanced version of the exercise program.
4. Participants report limited availability of exercise videos outside of class.	Participant telephone interview transcripts	4. Produce an exercise video with an entire set of repetitions readily available for course participants.
5. During iROLL sessions, some participants chose not to practice complex transfer and/or wheelchair skills.	Trainer telephone interview transcripts	5. Build in and schedule practice time in both trainer and participant manuals for each session. Add a prompt in both the trainer and participant manuals at practice time to highlight the critical nature of practicing skills. Cues could highlight the trainers' ability to support proper technique and potentially support fall management.
6. Trainers report occasionally having difficulty managing group dynamics.	Trainer telephone interview transcripts	6. Add a segment to the Training designed to help trainers proactively anticipate/identify challenging group dynamic situations that are commonly encountered and practice strategies to manage those situations. Use realistic iROLL case scenarios to support learning.
7. Trainers who delivered part of the intervention report unclear participant carryover across the intervention or from session to session.	Trainer telephone interview transcripts	7. Have at least one of the two trainers be consistent throughout all 6 iROLL sessions.
8. Trainers occasionally question iROLL's ability to support long--term behavior change with respects to fall self-management for participants.	Trainer telephone interview transcripts	8. Add home safety assessment/modification intervention to the program and/or referral to additional therapy services to support refinement of transfer skills/techniques for use in participants' natural home/community context.
9. For consideration: One participant reported a lack of accessibility (i.e., too much writing for his capability at the time) with study paperwork.	Participant telephone interview transcripts	9. Ask participants following study enrollment if they have any accommodation needs/considerations. Develop an option for participants to complete feedback and/or evaluation forms electronically. Options include: - utilizing his/her own preferred device (e.g., smart phone, laptop, tablet), with a link or application to support material - having a device available for participant use on site, such as a laptop or tablet with a readily accessible link or application to complete materials. In addition, an editable pdf of the manual that participants are able to modify (e.g., type in responses to questions, goal setting, take notes) as preferred could be provided.

Logistic fidelity ranged from 100% in Session 5 to 77.8% in Session 3. The only logistic-related fidelity item not consistently achieved was "starting on time". Qualitative notes from trainers highlight challenges with participants arriving late.

Content fidelity was high overall, ranging from 97.2% in Session 1 to 91.3% in Session 3. Key Session 3 challenges reported by trainers included difficulty navigating between trainer and participant manuals, audio-visual technical difficulties, the large amount of content to cover, and balancing didactic content with practice opportunities.

3.3.2. Dose findings

Each iROLL session was designed to last approximately 120 minutes. On average, sessions ranged from 106 (Session 4) to 118 minutes (Session 2).

3.3.3. Adaptation findings

The PI (LR) made one significant modification during the intervention based on feedback from the trainers. Specifically, because trainers reported difficulty using one manual describing session protocols and another covering session content, the PI consolidated the protocol and content material

Table 5
iROLL fidelity: findings from iROLL fidelity forms.

Session	Fidelity category	Fidelity items marked as completed by trainer	Total number of fidelity items	Calculated rating
Session 1	Logistic	17	18	94.44%
	Content	70	72	97.22%
Session 2	Logistic	13	15	86.67%
	Content	58	60	96.67%
Session 3	Logistic	14	18	77.78%
	Content	73	80	91.25%
Session 4	Logistic	12	12	100.00%
	Content	41	43	95.35%
Session 5	Logistic	12	12	100.00%
	Content	33	35	94.29%
Session 6	Logistic	16	18	88.89%
	Content	64	66	96.97%
Total	**Logistic Overall**	84	93	90.32%
	Content Overall	339	356	95.22%

into one trainer manual. Page number references for the participant manual were added to allow cross-referencing and ease use.

3.3.4. Reach findings

Reach-related data collected between March 2018 - April 2019 is summarized in Table 6. Attendance data by each site finds session 5 and 6 the most highly attended (100%) and session 4 the lowest attendance rate (81%). Overall session attendance was high at 93%. Participants reported challenges getting to and from the iROLL sessions (e.g., unreliable public transportation, time spent in commute), and 18 potential participants out of 48 screened (38%) declined to participate due to reported transportation, scheduling or required time commitment.

3.3.5. MOI findings

In the *Participant Post-Session Evaluations* participants provided a high overall satisfaction rating, 4.7/5.0, with Session 3 being the lowest (4.6/5.0) and Session 6 (5.0/5.0) being the highest. Per the *Post-Course Trainer Feedback Forms* iROLL trainers' level of satisfaction with the training to prepare them for iROLL delivery was high (4.6/5.0).

The overarching finding that emerged from the post-intervention trainer interview data was "diverse and interactive MOI". The study team selected the term "diverse" because the trainers described several important influences supporting the intervention's ability to support change in iROLL participants. The term "interactive" was used because many coded transcript statements were multi-coded, suggesting interaction between intervention features that together support outcome attainment. The five major themes related to iROLL's MOI were: *group dynamic, comprehensive nature of the program, strong program development, the role of a skilled interventionist, and motivated participants.* Each theme is described below. Table 7 describes the extent to which trainer interview findings were supported by additional data sources.

3.3.5.1. Group dynamic. Trainers consistently highlighted that the group dynamic supported program outcomes. The group dynamic allowed participants to draw from, and share their own skills and experiences which in turn facilitated group problem solving around fall prevention. The group dynamic also created a sense of accountability, comradery, and a safe space to consider one's own fall experiences and fall management strategies, while encouraging group members to learn from one another. The group occasionally challenged participants' belief systems about what pwMS are able to do, particularly with respect to community participation.

Trainer-07: …*participants really feed off each other and … on some level they trust or buy into their fellow participants' stories and strategies more than they would the professional…..*

iROLL participant-03: *And the whole camaraderie with the other group and the occupational therapists was very positive. It gives you a more positive outlook in life.*

3.3.5.2. Comprehensive nature of the program. The trainers valued iROLL's comprehensive approach to fall prevention which included purposeful attention to both content (i.e., material presented), and process (i.e., learning methods used). Content topics highlighted by trainers as being especially important included fear of falling, transfer training, and wheelchair skills. The trainers also commented on the value of the content that supported exercise-related behavior change. This support came in the form of reviewing the exercises, providing reminders to build exercise habits, offering a rationale to describe why an exercise was important, and explaining how to modify the exercise to meet user-specific needs. Participant's comments reflected their appreciation of iROLL's comprehensive nature. Areas that participants found important included: Opportunities to perform and self-evaluate transfer, wheelchair, and home exercise skills (Session 6; 4.9/5.0), information and training on MS symptom management skills related to falls prevention (Session 4; 4.9/5.0), and knowledge of Assistive Technology to manage fall risk (Session 5; 4.8/5.0).

Hands-on learning activities focused on creating a fall plan, goal setting, managing the environment through a home safety self-assessment, and action planning were specifically highlighted by trainers and then categorized as process-related strengths. Trainers also highlighted iROLL's ability to support participants' problem-solving and ability to create personalized plans to reduce fall risk. The trainers appreciated the varied learning activities (e.g., brief didactic presentations, practice opportunities, interactive group discussion), and commented that the discussions about the impact of disease progression on fall risk were especially meaningful. Finally, the trainers valued the many skills iROLL participants were able to build through practice opportunities, such as transfer skills, exercise technique, and wheelchair/scooter management skills. Overall, they commented on iROLL's ability to support pwMS at a variety of functional ability levels and found the participants' discussions about the impact of disease progression on fall risk to be beneficial.

Trainer-01: *the …information that focused specifically on chronic disease self-management things like the action planning, the goal setting, (and) reviewing the home exercise program week after week, trialing the home exercise program exercises together as a group (were valuable)…*

iROLL participant-02: … *I think it got me to focus both on my living environment, my personal space, and the environment at large, the outside the house. and …my wife and I got into a "what happens if I fall"? (discussion)*

Table 6
Summary of iROLL's reach (March 2018 to April 2019).

	Total
Screened	39
Enrolled iROLL participants	17
Did not pass screening	8
Declined due to time or scheduling	6
Declined due to hospitalization/exacerbation	1
Declined due to transportation/distance	7
iROLL participants who completed the intervention	17

3.3.5.3. Strong program development. The trainers' feedback reflected the value they placed on the evidence base supporting iROLL and the interprofessional approach to the development and delivery of the intervention. Trainers also reported that the integration of key topics throughout the program reinforced learning and supported outcomes.

Trainer-07: *The information … was also reinforced in several different ways …in the problem-solving scenarios, in the videos that were taught… so that the information was kind of presented in a number of formats, which I think helped reinforce learning and the potential for behavior change.*

iROLL participant-03: *…this program has helped me to focus more, to think about where my feet are, to make sure my wheelchair is off. All of those things you kind of knew, but this formally taught me, no you have to do this because it's safer.*

3.3.5.4. Role of a skilled interventionist. Trainers discussed the role that a skilled interventionist (i.e., trainers) has in supporting program outcomes. The key codes emerging in the data reflected specific trainer strengths: individualizing training in wheelchair/scooter skills, transfer skills and exercise techniques; providing participant specific feedback on action plans and performance of skills; and applying strong group management skills.

Trainers identified several unique group management skills needed to deliver iROLL. These skills included addressing specific needs of pwMS (e.g., cognitive changes, variable and/or progressive nature of the condition) and supporting the varied learning approaches within each session (e.g., group discussion, problem solving, lecture, practice, individualization, goal writing).

Table 7
MOI themes emerging from analysis of transcripts from trainer interviews and the extent to which those themes were supported by additional data sources

Source	Transcripts of 1:1 trainer telephone interview	Transcripts of 1:1 participant telephone interview	Participant post-session evaluations	Participant final course evaluation form	iROLL post-course trainer feedback forms
Key finding	Theme 1: Group dynamic	The small group was identified as a helpful program component within the participant program experience.	No comments provided on group dynamic in "Comments" section of this form.	Small group identified in open ended responses as a most helpful program component by participants.	Small group identified by trainers as one of the most essential elements of iROLL.
Summary	The positive impact of the group context on program outcomes was reflected upon all data sources, with the exception of Participant Post-session Evaluations.				
Key finding	Theme 2: Comprehensive nature of the program	Participant interview codes emerged including: action planning, video materials, fall recovery plans, environmental safety, transfer training, exercise, awareness and knowledge about available resources (e.g., insurance information, technology options), multiple sessions, w/c set up and maintenance.	Participant highest satisfaction ratings related to the value of the comprehensive nature of the program include: Opportunities to perform and self-evaluate transfer, wheelchair and home exercise skills (Session 6; 4.92/5.00), Information and training on MS symptom management skills related to falls prevention (Session 4; 4.92/5.00), Knowledge of assistive technology to manage fall risk (Session 5; 4.83/5.00)	Participants rated several different program components as being helpful. These program components included (N = number of participants): exercise (6), transfer training (6), experienced trainers (3), and the training materials/resources (3).	Post course trainer feedback found several elements considered essential to iROLL, including (N = number of trainers): small group (8), practice time (3), repetition/reinforcement (2), goal setting (1), videos (1), environment (1), exercise log (1), and w/c maintenance (1).
Summary	Trainers and participants identified qualities related to the comprehensive nature of the program consistently across data sources.				
Key finding	Theme 3: Strong program development	No comments directly noted.	Participants rate a high overall satisfaction (4.65/5.00), with session 3 being the lowest (4.55/5.00) and session 2 and 6 (4.71/5.00, respectively) rated the highest.	Participants rated the overall value of iROLL's content to help you manage falls as 4.67/5.00.	Highest trainer-rated content areas that impact outcomes included: improve community participation (4.78/5.00), improve knowledge and management of fall risk factors (4.78/5.00), and minimize fear of falling (4.75/5.00).
Summary	Data from post-intervention trainer interviews was unique and reflected trainers' views that iROLL's evidence base, integration of themes and interdisciplinary development were strengths. Additional sources reflected trainers' and participants' views that iROLL's program was valuable to help manage falls.				
Key finding	Theme 4: Role of the interventionist	Under program experience, the theme of "Experienced Trainers" was highlighted amongst participants.	No comments provided on role of the interventionist in "Comments" section of this form.	At the final course evaluation, participants rated the following with respect to the trainers: Instructor's knowledge of the course content (5.0/5.0); Ability of course and instructor to motivate you to try new fall prevention strategies (4.75/5.00); Instructor's ability to present course material and to facilitate discussion (4.67/5.00)	Average rating on the adequacy of the training to prepare for iROLL delivery was 4.63/5.00. Most helpful aspects of the training included strong communication with the Master Trainer, session break downs, and supplemental videos.
Summary	Across both participant and trainer data sources, with the exception of Participant post-session evaluations, the role of experienced and skilled trainers was discussed. Ability to present material, facilitate discussions, support symptoms/experiences unique to pwMS and adapt/modify the intervention as needed were articulated as key trainer strengths. Trainers' feedback reflected that they felt prepared to deliver iROLL.				
Key finding	Theme 5: Motivated participants	Participant interviews highlight the following motivations to participate in iROLL: gain information/skills, prevent falls, support MS research. The group also supported motivation, particularly with exercise participation.	No comments provided on motivated participants of this form.	No comments on motivated participants identified on this form.	No comments provided on motivated participants identified in this form.
Summary	Qualitative interview data from trainer and participant sources included comments regarding the participants' motivation to participate in iROLL. For example, trainer interview data included comments regarding participants' follow through with homework and high session attendance. Participants discussed the intrinsic motivations of choosing to engage in the intervention, such as to gain information/skills related to fall prevention and to support MS research.				

Trainer-04: …*engaging people in discussions, … where you're leading the discussion, but you're allowing them to kind of think through some of the issues, leaving room and space for open comment is really helpful in facilitating people, problem solving their own issue.*

iROLL participant-03: …*just the practice of it, having formal instruction of how to do it, all of that just really helped me think about it and just do a better job.*

3.3.5.5. Motivated participants. The final major sub-theme that emerged captured the trainers' view that participants were motivated to engage and participate in the iROLL sessions. Both the group process and the repeated goal setting motivated participants, from the trainers' perspective.

Trainer-04: …*having people be accountable to the group is helpful, motivating the change…*

iROLL participant-08: *when we do it (exercises) together, it motivates me.*

4. Discussion and conclusion

4.1. Discussion

iROLL is the first comprehensive intervention designed to meet the fall prevention and management needs of pwMS who use wheelchairs or scooters full-time. Importantly, process evaluation results indicate that iROLL is acceptable to the intended end users. Together, findings reflecting the high attendance rates and the high level of participant satisfaction indicate that iROLL participants view the intervention content as relevant. The iROLL trainers and participants also valued the intervention processes, which included group-based opportunities for peer modeling as well as opportunities to practice and master a variety of fall prevention and management skills. The program can be implemented as intended based on findings pertaining to fidelity, dose, and adaptations. Adequate training of the therapists implementing the intervention was particularly salient to support fidelity.

Findings from the data related to MOI pointed to the value of diverse learning activities (e.g., lecture, group discussion) and the importance of practice opportunities to build self-management skills. iROLL processes supported a variety of learning styles and made it possible for participants to create and use fall prevention strategies that worked best for them, in the context of their day-to-day life. Using self-management skills in the context of a fall prevention interventions is consistent with the most widely disseminated fall prevention program for older adults (e.g., *Matter of Balance*) [26] and fall management programs specifically designed for pwMS, such as the *SAFE at Home BAASE* program [24]. Our findings directly address the observation by Frasier, et al. regarding the lack of knowledge on the effective elements of self-management programs for people with MS [27] by documenting that iROLL trainers identified problem solving, action planning as program strengths. They also spoke to the value of the practice (skill mastery) opportunities and the group-based processes that provide opportunities for peer modeling, both of which are important positive influences on self-efficacy.

Effective delivery of iROLL requires a particular skill set, which is reflected in the *role of the skilled interventionist theme*. Specifically, trainers must support and balance robust and dynamic discussions with the didactic content and practice opportunities within each session. Trainers must also be able to work collaboratively with the group to support problem solving and solution finding. Although manualized, delivery of iROLL also requires trainers to adapt and adjust the content (e.g., modify transfer techniques) to meet group members' individual needs, while maintaining program fidelity. Trainers must be capable of helping participants practice skills ranging from action planning to transfers. Trainers who effectively use practice experiences to create opportunities for peer modeling and skill mastery are most effective in building participants' falls self-efficacy [13].

Our systematic assessment of program reach resulted in a strong understanding of the recruitment challenges that must be addressed in future program improvement efforts. The transportation and scheduling challenges reported by iROLL participants and eligible individuals who declined study involvement are similar to challenges reported by other MS researchers [28]. Although we proactively utilized multifaceted recruitment strategies as recommended [28], barriers to program access for our non-ambulatory target population must be addressed. Recognizing growing interest in telerehabilitation delivery for evidence-based interventions for pwMS [29,30] our research team will explore telerehabilitation program delivery options that retain iROLL's fidelity and strong group dynamic. A hybrid approach involving both telerehabilitation and face-to-face intervention components may allow for the skill mastery opportunities valued by iROLL participants.

This study has several limitations to consider. A small sample of both trainers and iROLL participants provided data associated with this process evaluation. As outlined by Merriam & Tisdell [31], an adequate sample size is determined by data saturation. Although data saturation began to emerge, additional participants may have had expanded findings. It is notable that selection bias may have occurred in that participants who were either more motivated and/or more comfortable with the intervention approach may have been more likely to participate. Additionally, iROLL session fidelity was measured via trainer self-report. Staff members' involvement in fidelity assessment would yield a more objective assessment. Also, dose *delivered* was measured, but not dose received. In future process evaluations, quantifying dose received by asking participants to report on time spent reviewing intervention videos demonstrating transfer and wheelchair skills, practicing fall prevention skills, and time spent reviewing iROLL participant handouts would yield a more comprehensive assessment of program implementation. Although monitoring iROLL participants' long-term adherence to behaviors and skills taught in the intervention was beyond the scope of the present study, future investigations of intervention adherence at 6- and 12-months post-intervention are warranted. Finally, subsequent process evaluations associated with investigations of iROLL's effectiveness will be enhanced with attention to the context in which the intervention was delivered.

4.2. Innovations

Preventing falls is an important public health priority and is particularly salient for those with health conditions like MS, which can lead to mobility problems, cognitive changes, weakness, fatigue and spasticity (32). In addition, there is limited research and evidence-based interventions related to this topic. iROLL is the only peer-reviewed fall management and prevention program designed for pwMS who use a wheelchair or scooter [5], is feasible to implement, and acceptable to the target population. Adequate training, trainer support, and quality manuals enhance program implementation. iROLL's comprehensive fall prevention and management materials, varied learning approaches/processes, and group structure supports the impact of the program and participant satisfaction. Future iterations of iROLL will benefit from exploring on-line delivery to address the challenges with program reach.

4.3. Conclusion

This study reports the outcome of a process evaluation of iROLL, with a particular emphasis on program implementation and MOI. The process evaluation efforts undertaken effectively identified key strengths, limitations and recommendations for future iterations of the intervention. Findings highlighted that iROLL was implemented successfully and yielded valuable insights into how the intervention works. Although recruitment and reach were challenges, diverse and interacting MOI support attainment of outcomes sought. Findings suggest distance education delivery methods that maintain the group dynamic may improve program reach.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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