Fewer Falls in MS - A fall prevention intervention for people with multiple sclerosis: Pilot study findings and implications for occupational therapy's role in fall prevention

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Authors

Elizabeth W. Peterson, PhD, OTR/L, FAOTA[1]

Ulrika Meijer, MSN[2]

Marie Kierkegaard, PhD[2]

Susanna Tuvemo Johnson, PhD[2]

Johanna Bylinder, PhD candidate[2]

Kristina Gottberg, PhD[2]

Maria Flink, PhD[2]

Charlotte Ytterberg, PhD, reg physiotherapist[2]

[1]University of Illinois Chicago, Department of Occupational Therapy, Chicago, Illinois, USA

[2]Karolinska Institutet, Department of Neurobiology, Care Sciences & Society, Huddinge, Sweden

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Presentation Objective:

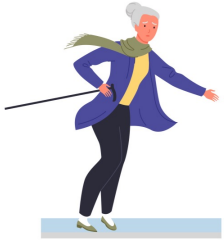
To describe the *Fewer Falls in MS* pilot study findings & implications.

Background: Multiple Sclerosis (MS)

- Multiple sclerosis (MS) is a chronic, inflammatory, demyelinating, and neurodegenerative disease of the CNS.
- Approximately 2.9 million people are affected by MS globally,[1]
- Clinical symptoms depend on the extent & distribution of demyelinating lesions throughout the CNS.
- MS has the potential to lead to a variety of body-function impairments, activity limitations & participation restrictions, which can increase the risk for a fall.

[1] Walton et al. 2020.

Background: Falls & MS



- Falls are common among ambulatory and non-ambulatory people with MS (PwMS).[1,2]
- 30% of PwMS who fall report injurious falls.[3]
- 64% of PwMS report fear of falling. [4]
- PwMS have unique fall prevention needs.
    - Multifactorial influences on fall risk necessitate comprehensive interventions.[3]

[1] Gunn et al. 2013

[2] Rice et al. 2017

[3] Abou et al. 2024

[4] Peterson et al. 2007

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Background: Status of MS Fall Prevention Research

- Fall prevention research involving ambulatory PwMS is a growing area of inquiry.

- Few interventions address the needs of non-ambulatory PwMS.

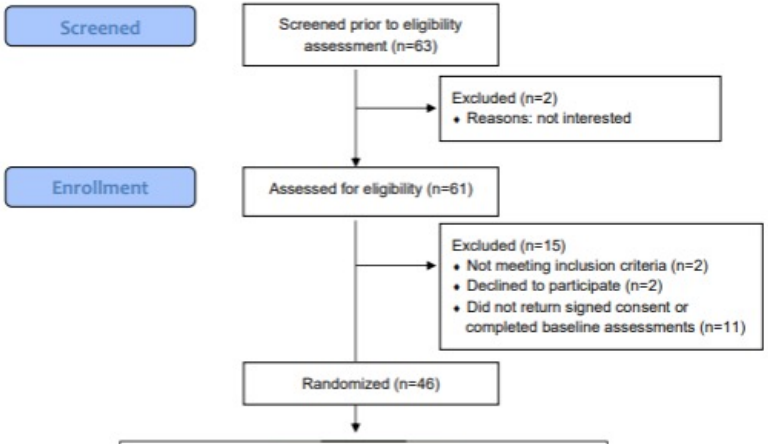
Overall Study Aim & Method

Study Objective

To evaluate the feasibility and outcome of the *Fewer Falls in MS*, to inform the decision on whether to proceed to a full-scale RCT.

Method

A two-armed parallel group pilot RCT. *



*Approved by the Swedish Ethical Review Authority. Registered at Clinical Trials.

Specific Study Objectives

- **Feasibility**
  - recruitment process
  - data collection procedures
  - intervention delivery
  - outcome measures
- **Participant retention**
- **Session adherence**
- **Outcome**
  - between- and within-group differences
- **Adverse events**
- **Acceptability**
  - for persons with MS
  - for group leaders
- **Fidelity**
  - intervention fidelity during delivery

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Participants & Recruitment

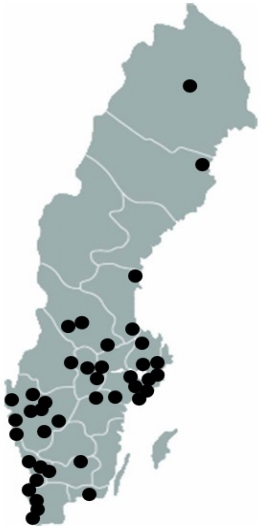
Participants

- ambulatory & non-ambulatory* PwMS
- aged ≥ 18 years
- able to understand and communicate in Swedish
- had access to and the self-rated ability to use, technical devices for online meetings
- capable of giving informed consent.

* Nonambulatory = Unable to walk beyond 5 m even with aid; able to independently transfer bed > wc, with or without aids.

Recruitment

- 2 outpatient neurology clinics in Stockholm
- (Patient organization) Neuro Sweden



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The Intervention: *Fewer Fall in MS*

- A theory-based, online fall prevention self-management program for ambulatory and non-ambulatory PwMS.
- Key outcomes:

  -improved falls self- efficacy, which is now referred to as Concerns about Falls (CaF)[1]

  -reduced fall incidence

[1] Montero- Odasso et al. 2022

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The Intervention: *Fewer Fall in MS* > Development

Features

- Scoping review-self-mgmt. & fall in PwMS [1]
- A carefully operationalized definition of self-management.[2]
- An iterative co-design process [3] involving
  - PwMS
  - healthcare professionals on MS teams
  - researchers

[1] Tuvemo Johnson et al. 2023

[2] Lorig & Holman 1993

[3]Johnson et al. 2024

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The Intervention: Content & Processes

Content

- Based on Social Cognitive Theory & Universal Design for Learning
- **Key Topics**
  - influences on fall risk
  - prevention strategies
  - behavior change process
  - goal setting & action planning
  - maintaining motivation

Processes

- Manualized, group intervention
- Delivered by a health care professional
- 6 (2-hour) weekly group sessions, assignments) + booster
  - Interactive lectures, peer learning > goal setting, action planning, self-evaluation
- Zoom- based in real time/F2F
- Canvas learning mgmt system

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Intervention Feature: Action Planning Process

Control Condition

- Both IGPs and control group participants (CGPs) received a b
  informational brochure
  - provided via email.
  - Included information about fall risk for PwMS &
    practical tips on reducing fall risk in everyday life.
  - Content was designed to be accessible & relevant for individuals with varying levels of disability.

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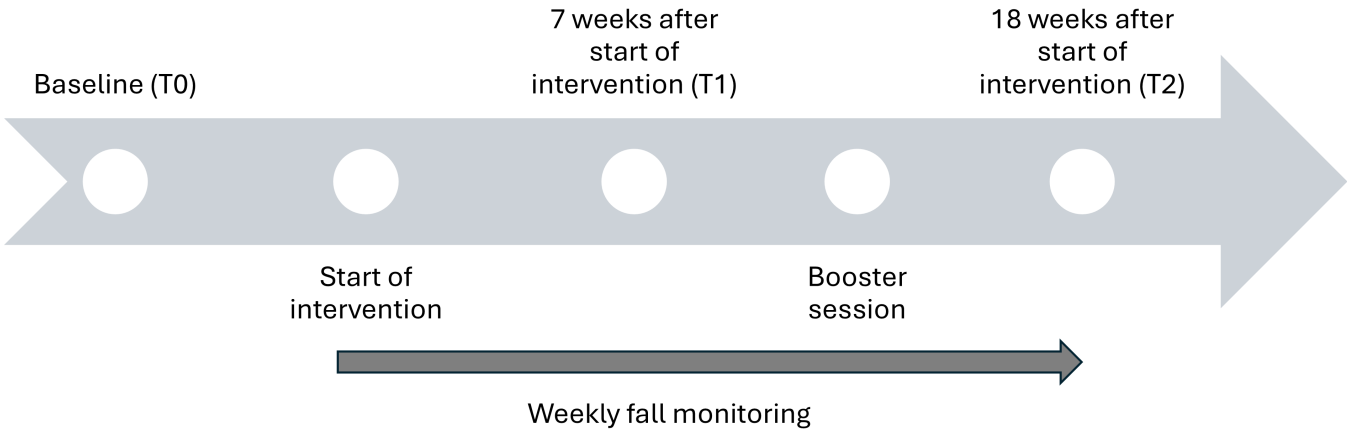
Assessment of Study Objectives: Examples of Strategies Used

Feasibility of data collection & recruitment	Based on time needed to complete.
Feasibility of intervention delivery	# sessions completed; occurrence of technical issues.
Feasibility of outcome measures	Based on participants' experiences T2, ceiling & floor effects.
Participant retention	# remaining in trial; # dropouts + reasons.
Session attendance	# Intervention group participants (IGPs) attending sessions.
Intervention outcomes	Between- and within group differences
Adverse events	Follow-up phone calls post-fall

Data Collection for *Fewer Falls in MS* Outcomes: Timeline

Questionnaire data were collected at **3** timepoints:

- at baseline (T0),
- 7 weeks after the start of the intervention (T1) i.e., at the end of the program but *before* the booster session,
- 18 weeks after the start of intervention (T2).



Data Collection: Falls Monitoring, Fidelity & Feasibility

Falls* Monitoring

- Weekly SMS
- If “yes” > follow up interview

*Fall = an unexpected event in which the participants come to rest on the ground, floor, or lower level”[1] .

[1] Lamb et al. 2005

Fidelity & Feasibility

- Research team members observed each session.

  -Structured observation protocol used.

  -Facilitators’ reflections after each session.

  -Semi-structured interviews.

Data Collection: Standardized Questionnaires

Outcome	Tool used
Fall prevention behaviors	Fall Prevention Strategies Survey (FPSS)
Fear of falling	VAS-Fear of falling
Falls self-efficacy/CaF	Falls Efficacy Scale-Internat'l (ambulatory)
Falls self-efficacy/CaF	Spinal Cord Injury-Falls Control Scale (non-amb)
Frequency of IADLs	Franchay Activities Index (FAI)
Physical & psy. Impact of MS	Multiple Sclerosis Impact Scale
Physical activity (PA)/week	Physical Activity Questionnaire
Time spent sitting/day	Sedentary Behavior Questionnaire

Statistical Analysis

- Normally distributed data reported with mean, SD, range.
- Non-normally distributed data reported with median, IQR.
- Categorical data summarized using frequencies & percentages.
- Non-parametric statistics applied for standardized questionnaire data.
- Between-group differences at T2- Mann–Whitney U test (I) samples.

  - Exception: PA & sedentary behavior tools-Chi-square test applied.
- Within-group differences-Friedman test for related samples.

  - Exception: PA & sedentary behavior-Cochran's Q test used.
- Parametric statistics (independent t tests) used to compare # falls, fall incidence (falls/person/ year) &injurious fall incidence (injurious falls/person/year) between groups.

  Intention-to-treat approach was adopted.

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Results: Participants

		Intervention (n=23)	Control (n=23)
Age, mean (min-max) years		58 (43-72)	57 (39-72)
Sex	Women	20	18
	Men	3	5
Walking ability	No difficulties, n	6	6
	Can walk 20-500 m, n	13	13
	Cannot walk 5 m, n	4	4
Fall last 3 months, n		12	16

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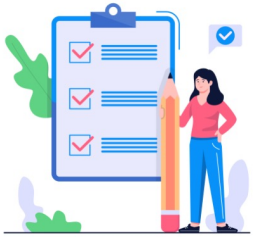
Results
(For additional detail, refer to Handout)



	Assessment Objective
√	Feasibility: recruitment
√	Feasibility: data collection
√	Feasibility: intervention delivery
√/-	Feasibility: outcome measures
√	Participant retention
√	Session adherence
-	Outcomes of intervention >> * Pilot not powered to detect significant changes between/within groups.
√	Adverse events

- No statistically significant between or within group differences at T2.
  - Exception= ↑ FAI scores over time for IG.
- Non-statistically significant trend for less falls among IG compared with CG (mean difference −3.9, 95% CI − 8.9 to 1.1; p=0.12),
  - 15 ICGs reported 37 falls
  - 17 CGPs reported 70 falls

Discussion

- *Fewer Falls in MS* is a novel & feasible intervention.
  - developed in collaboration with stakeholders
  - targets both ambulatory and non-ambulatory PwMS
  - focuses on self-management
  - delivered online
- Meeting all but one progression criteria (relevance of outcome measures) justifies proceeding to a full-scale RCT.
- Insights gained support study refinement.
  - Adding (+) fall history as an inclusion criteria
  - Adding an initial orientation session to ↓ technical difficulties
  - Some modifications to outcome measures

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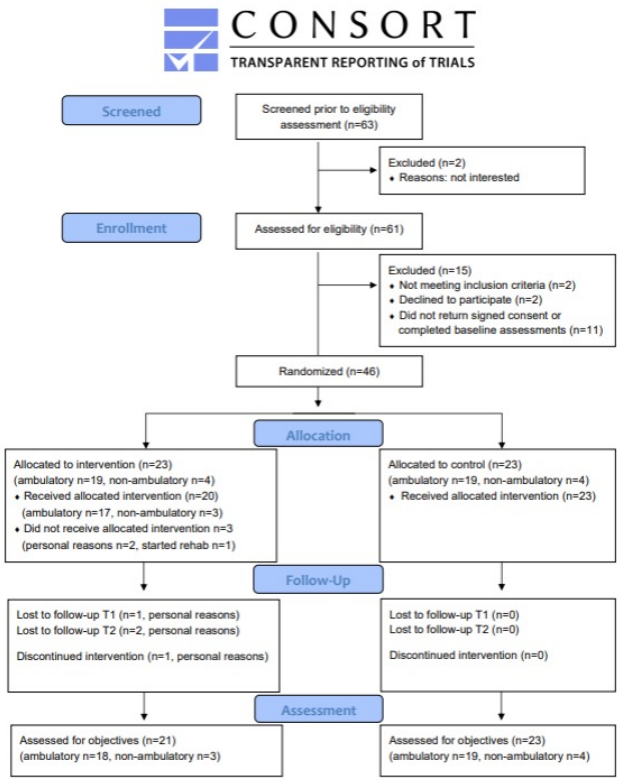
Conclusion

- Findings underscore the need for a fully powered RCT to evaluate the intervention's effectiveness in reducing CaF & incidence of falls.
  - larger sample size & longer follow-up period needed to enable subgroup analyses.



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epeterso@uic.edu

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