Study protocol & Statistical analyses plan

Official title: Digitally Supported Intervention to Master Complex Fall Risk Situations in Persons with Multiple Sclerosis – a Multicenter Study (STAR)

Brief title: Intervention to Master Complex Fall Risk Situations in Persons with Multiple Sclerosis (STAR)

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Background Fifty-six percent of those with a mild to moderate multiple sclerosis (MS) report falls during a three-month period and 60 % express fear of falling. Several fall risk factors have been identified a complexity of falls including the interaction of triggering factors and preceding activities and events has been described. There is a lack of studies explicitly evaluating fall prevention strategies given as counselling over time.

Methods This is a two-armed internal pilot study with a parallel group design and random allocation to control or intervention group (1:1). The pilot study will evaluate feasibility in terms of recruitment, drop-outs, adverse events and battery of tests, and constitute the base for recalculation of the beforehand estimated sample size for a full-scale study. The full-scale study will evaluate whether a fall preventative strategy based on individual fall risk evaluation will reduce fall frequency compared to general fall preventative information. The hypothesis is that the intervention group will report 30% less falls during the 6-months period when the intervention is active, compared to the control group. Based on descriptions of recent fall situations, fall risk factors will be categorized using the International Classification of Functioning, Disability and Health. Participants in the intervention group will discuss the impact from specific MS-symptoms, environmental and personal factors, triggering factors and activities and/ or circumstances that the individual perceive precede fall situations with the physiotherapist leading to individual strategies. The control group will receive general fall risk

prevention recommendations. After completion of the study, the control group will be offered individual strategies based on reported falls.

Adults diagnosed with MS, fall history and remained walking ability will be recruited in six sites in Sweden by physiotherapists. Primary outcome is self-reported falls during six months. Secondary outcomes are self-rating scales focusing on concern of falling, confidence in remaining balance during activities, walking limitations and ability to avoid falls.

Table 1. Participant timeline: Schedule of enrollment, interventions, and assessments.

	TRIAL PERIOD			
	Enrollment	Allocation	Post-randomization	Follow-up
TIMEPOINT[b]	$-t_1$	t_0	t_2 *For 6 months*	t_3
ENROLLMENT:				
Eligibility screen	X			
Informed consent	X			
Check for inclusion and exclusion criteria		X		
Randomization		X		
INTERVENTION/ COMPARATOR:				
Individual fall preventative strategy as add-on to general fall risk information)		X	→	
General fall risk information[d]		X	→	
ASSESSMENTS:				
*Demographic data *, Timed Up and Go test, Six Spot Step test, Symbol Digit Modalities test, 29-item MS Impact scale*		X		
Number of falls, falls description, injury due to fall, need to seek care due to fall, adverse events.		X	→ *Every two weeks.*	
Falls Efficacy scale International, Activities-specific Balance Confidence scale, 12-item MS Walking scale, Frändin Grimby Physical activity scale, Fear of falling, Avoid activities due to fall risk, Master fall risk, Understanding fall risk factors, Self-rated change in balance		X		X

*Sex, gender, MS-type, falls last 3 months, ongoing physiotherapy/rehabilitation, walking device, occupation, living condition, contact information**exacerbation, ongoing physiotherapy/rehabilitation, changes in walking device use, living condition or occupation

Statistical methods

The flow of participants through the study will be examined and illustrated according to the Consolidation Standard of Reporting Trials (CONSORT) (1). We will calculate the proportion of participants lost to follow-up.

Analyses will be performed on an intention-to-treat basis. Baseline demographic and clinical characteristics of the study participants will be summarized for the two intervention groups separately. Continuous variables will be summarized using the measures of central tendency and dispersion (mean and standard deviation, the median and interquartile range as well as minimum and maximum values) as appropriate based on the distribution. Categorical variables will be summarized using frequencies and percentages. Since baseline characteristics are expected to be balanced between intervention groups due to randomization, we will evaluate if any substantial imbalance may have occurred by chance.

The distribution of outcome data will be examined. For the analysis of primary outcome, we will consider Poisson regression if the assumptions are satisfied or Negative binomial regression, which relaxes the assumption made by Poisson regression that the variance is equal to the mean. We may consider also Cox regression to compare time to the first fall between intervention arms. Since falls may occur repeatedly in patients with MS, we may consider also extensions of Cox proportional hazards regression that are for recurrent event analyses. Estimates unadjusted and adjusted for baseline covariates will be presented. Secondary outcomes will be analyzed according to the measurement type and distribution.