

From DEPARTMENT OF NEUROBIOLOGY, CARE SCIENCE AND  
SOCIETY, DIVISION OF PHYSIOTHERAPY

Karolinska Institutet, Stockholm, Sweden

# **Falls in Ambulatory Individuals with Spinal Cord Injury**

## **Incidence, Risk Factors and Perceptions of Falls**

Vivien Jørgensen



**Karolinska  
Institutet**



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**FALLS IN AMBULATORY INDIVIDUALS WITH SPINAL CORD INJURY -  
Incidence, risk factors and perceptions of falls**  
THESIS FOR DOCTORAL DEGREE (Ph.D.)

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## FOREWORD

I never thought I would go on this Ph.D. trip, but after some consideration and persuading from others, I seized the opportunity and have not regretted a second. The trip has been like climbing a mountain; challenging, demanding, breath-taking, putting my patience and stayer ability to the test, but with nice views during the climb.

When I started my training as a physiotherapist in Bergen a long time ago, there was a possibility that the school had to stop after half a year due to lack of final governmental approvals. History tends to repeat itself; this Ph.D. trip was also hampered by complications the first year. The financial supporters required a Norwegian Ph.D., giving me the option of defending the thesis both in Norway and in Sweden. However, this solution never worked out, and the external financing went up in smoke! Sunnaas Rehabilitation Hospital generously decided to finance the Ph.D., and I could carry on with only one defence in sight and less burdensome reporting!

I have fallen, figuratively as well as literally during this Ph.D. trip. In fact I have fallen more than many of the participants, and ironically my summer holiday in the mountains also went up in smoke because of a fall. Lesson learned; Falls can be harmful. Moreover, falls can be devastating; nearly half of those who acquire a spinal cord injury today do so in a fall. Fortunately, falls can be comic as well, at least when there are no injuries. A female participant, who was dining out with a friend, fell when transferring from the HC-toilet to the wheelchair because the toilet tilted! Just imagine the woman lying on the floor with the water splashing around and her make up flowing down her face, hoping that she had flushed the toilet! Luckily no one was looking! She had an excuse from the restaurant and a taxi back home and an amusing story to tell. Lesson learned; check the toilet screws as the plumber may have forgotten to tighten the screws after repairs!

Experiences through a long working life, has been of great help. I'm also very grateful to my late parents. My mum Eileen Carol gave my basic skills in English language which has been of great help in this work. My father Arvid told me patience and hard work through the slogan; 'Do as the ant, one needle at the time and you will finally have your anthill'.

This Ph.D. trip has given me new insights, new friends and colleagues, some frustrations, a lot of fun and a range of other experiences and possibilities. However, growing up in a mountainous country, I know that when one top is reached, there soon will be new ones in sight. No reason to rest on the laurels!



# ABSTRACT

**Background:** Falls in ambulatory individuals with chronic spinal cord injury (SCI) are common and may have adverse consequences. Little and inconclusive research has been done in this population, and there is a need for more knowledge in order to develop prevention strategies appropriate for this population.

**Aim:** The overall aim of this thesis was to study the incidence of and identify the risk factors for recurrent (>2) and injurious falls in ambulatory individuals with SCI.

**Method:** A consecutive sample of 224 individuals with chronic ( $\geq 1$  year) traumatic SCI and at least 18 years old attending regular follow-up programs at two rehabilitation centres located in Norway and Sweden, were included. Individuals with complete motor lesions above C5 (AIS A and B) or lesions below were excluded. At baseline data believed to be important for falls and fall-risk were collected through interviews, clinical tests, questionnaires including fall history the previous year. The following 12 months falls were monitored using an automatic short message service (SMS) posted every second week. The participants answered 'yes' or 'no' to the question: 'Have you been falling the past two weeks? A positive answer was followed by a structured telephone interview. The number of falls, fall-related injuries and severity of the injuries as well as the perceived causes of the falls were registered.

**Results:** *Study I*, a cross-sectional study (n=224) including both wheelchair users and ambulatory individuals, found that 73 per cent of the participants reported falling and 51 per cent reported recurrent falls (>2) the previous year. Ambulatory, younger and active individuals had higher risks of recurrent falls, and different factors were associated with recurrent falls in ambulatory individuals and wheelchair users. *Study II*, a longitudinal observational study, included the ambulatory subgroup (n=68). Fifty-six (82%) of the participants reported falling and 33(48%) reported recurrent falls. Of 272 reported falls, 41per cent were injurious. Four per cent, all women, experienced serious injuries. Reporting recurrent falls the previous year and fear of falling could predict recurrent and injurious falls. Reduced maximal walking speed was also a predictor of recurrent falls. *Study III* included a purposeful sample of 15 ambulatory individuals who shared their experiences and perceptions on falls, risk of falling and fall-related consequences. The participants considered falls to be part of life and took precautions, but were also willing to take risks if important for self-image. However, falls in every-day situations interfered with their self-image as healthy and well-functioning. A few expressed inexpedient concerns about falling. *Study IV*, a methodological study, validated and compared the psychometric properties of two balance scales; the Berg Balance Scale and the Mini-BESTest in 46 individuals able to walk 10 metres. Both scales were valid, but the Mini-BESTest seemed to be preferable in ambulatory individuals with SCI due to lack of ceiling effect, better responsiveness and better scaling properties.

**Conclusion:** Falls and injurious falls were common in ambulatory individuals with SCI. A history of recurrent falls and fear of falling could predict recurrent and injurious falls. In addition slower maximal walking speed was a predictor of recurrent falls. Participants considered falls to be a part of life, but falls affected self-identity as 'normal' and well-functioning. Mini-BESTest was the best scale for measuring balance control in this group. The studies show that there is a need for fall prevention measures adapted for the ambulatory SCI population.

# SAMMANFATTNING

**Bakgrund:** Falls hos gångare med kronisk ryggmärgsskada (RMS) är vanligt och kan få negativa följder, dock är detta ett relativt outforskat för denna grupp och resultaten är inte entydiga.

**Syfte:** Det övergripande syftet med denna avhandling var att studera förekomsten av, och identifiera riskfaktorer för, återkommande fall (>2) och fall med skada hos gångare med RMS.

**Metod:** Ett konsekutivt urval på 224 personer med kronisk ( $\geq 1$  år) traumatisk RMS, och minst 18 år gamla som deltog i regelbundna uppföljningsprogram på två rehabiliteringscentra i Norge och Sverige, ingick. Personer med AIS A och B ovanför C5 eller skador nedom L5 exkluderades. Vid baslinjemätningen blev deltagarna intervjuade, undersökta och fick svara på frågeformulär om variabler som antogs vara viktiga för fall och fall risk, tex om fall föregående år. Fall registrerades under ett år via sms varannan vecka med frågan 'Har du fallit de senaste två veckorna?' Vid fall gjordes en telefonintervju om antal fall, fallskador upplevd orsak till fall.

**Resultat:** *Studie I*, en tvärsnittsstudie (n = 224) med både rullstolbrukare (n=151) och gående personer (n=73), fann att 73 procent av deltagarna rapporterade att de fallit föregående år och att 51 procent rapporterade återkommande fall (>2). Gående, yngre och aktiva individer hade högre risk för återkommande fall, och olika faktorer var associerade med återkommande fall hos gångarna och hos rullstolsburna. *Studie II*, en 12 månader longitudinell observationsstudie, inkluderade enbart gångarna (n = 68). Femtiosex (82%) av dessa rapporterade fall och 33 (48 %) rapporterade återkommande fall. Av 272 rapporterade fall, ledde 41 procent till skada. Fyra procent, alla kvinnor, ådrog sig allvarliga skador. Återkommande fall föregående år och rädsla för att falla predicerade återkommande fall och fall med skada. Lägre maximal gånghastighet predicerade också återkommande fall. *I studie III*, en kvalitativ intervjustudie med 15 gångare om erfarenheter av, och uppfattningar om, fall, fallrisk och konsekvenser av fall. Deltagarna ansåg fall att var en del av livet; de var försiktiga, men tog också risker. Fall i vardagssituationer påverkade deras identitet och självbild som friska och välfungerande. Några få uttryckte stor oro för att falla. *I studie IV*, en valideringsstudie med 46 personer som kunde gå minst 10 meter, jämförs de psykometriska egenskaperna till två balansskalor; Berg Balance Scale och Mini-bestest. Båda skalorna visat sig vara valida, men Mini-Bestest passade bäst för denna grupp då den hade bättre mätgenskaper och saknade takeffekt.

**Slutsats:** Fall och fallskador var vanligt ibland gångare med RMS. Återkommande fall tidigare år och rädsla för att falla kunde predicera återkommande fall och skadliga fall. I tillägg var långsammare maximal gånghastighet en prediktor för återkommande fall. Mini-BESTest var bästa valet av balansskala för denna grupp. Deltagarna i intervjustudien ansåg att fall var en del av livet, men att fall rubbade deras självidentitet som frisk och välfungerande. Studierna visar att lämpliga fallförebyggande åtgärder anpassade till gångare med RMS behövs.



# LIST OF SCIENTIFIC PAPERS

This thesis is based on the original papers listed below. In the text, they are referred to by their roman numerals.

- I     Jørgensen V\*, Butler Forslund E\*, Franzén E, Opheim A, Seiger Å, Ståhle A, Hultling C, Stanghelle JK, Wahman K, Roaldsen KS  
*Factors associated with recurrent falls in individuals with traumatic spinal cord injury – a multi-center study*  
\* Shared first authorship  
Archives of Physical Medicine and Rehabilitation 2016 (In press)  
DOI: 10.1016/j.apmr.2016.04.024
- II    Jørgensen V, Butler Forslund E, Franzén E, Opheim A, Seiger Å, Ståhle A, Hultling C, Stanghelle JK, Wahman K, Roaldsen KS  
*Falls and fear of falling are risk factors for future falls and related injuries in ambulatory individuals with spinal cord injury: a longitudinal observational study*  
Submitted and under revision
- III   Jørgensen V, Roaldsen KS  
*Negotiating identity and self-image: Perceptions of falls in ambulatory individuals with spinal cord injury – a qualitative study*  
Clinical Rehabilitation 2016 (Epub ahead of print).  
DOI: 10.1177/0269215516648751
- IV    Jørgensen V, Opheim A, Halvarsson A, Franzén E, Roaldsen KS  
*Comparison of Berg Balance Scale and Mini-BESTest for assessing balance in ambulatory individuals with spinal cord injury – a validation study*  
Submitted

Paper II and IV may undergo changes before journal publication.

# CONTENTS

1	INTRODUCTION .....	1
1.1	Spinal cord injury .....	2
1.1.1	Definitions .....	2
1.1.2	Aetiology .....	4
1.1.3	Incidence and prevalence of SCI .....	4
1.1.4	Demographic characteristics in Western countries .....	5
1.1.5	Rehabilitation and lifelong follow-up.....	5
1.1.6	The importance of walking .....	5
1.2	Falls and adverse consequences of falls .....	6
1.2.1	Definitions .....	6
1.2.2	Falls .....	6
1.2.3	Fall-related injuries .....	6
1.2.4	Fall-related psychological aspects .....	7
1.2.5	Risk factors for falls and fall-related injuries .....	7
1.3	Balance control.....	8
1.3.1	Definition.....	8
1.3.2	Balance control in SCI .....	8
1.3.3	Assessment of balance control.....	9
1.4	Measurement properties of assessment tools.....	10
1.5	Rationale for this thesis .....	11
2	AIMS .....	13
3	MATERIAL AND METHODS .....	15
3.1	Design .....	15
3.2	Ethical considerations .....	16
3.3	Participants.....	16
3.3.1	Inclusion and exclusion criteria .....	16
3.3.2	Sample sizes .....	17
3.3.3	Recruitment and inclusion .....	17
3.4	Data collection.....	19
3.4.1	Outcome measures .....	19
3.4.2	Qualitative interviews .....	27
3.5	Data analysis.....	27
3.5.1	Studies I and II .....	28
3.5.2	Study III.....	29
3.5.3	Study IV.....	30
4	RESULTS .....	31
4.1	Participants.....	31
4.2	Falls and associated factors in individuals with SCI .....	33
4.3	Falls, injurious falls and their predictors in ambulatory individuals with SCI....	34
4.3.1	Additional results .....	35
4.4	Individual perspectives on falls and fall risk.....	38
4.5	Assessments of balance control.....	40
4.5.1	Additional results .....	42

5	DISCUSSION .....	47
5.1	Main findings .....	47
5.2	Falls.....	48
5.3	Adverse consequences of falls.....	48
5.3.1	Fall-related injuries .....	48
5.3.2	Fall-related psychological aspects .....	49
5.4	Fall risk and risk factors.....	51
5.5	Falls and balance control .....	52
5.6	Methological considerations .....	53
5.6.1	Sample representativity .....	53
5.6.2	Sample sizes .....	53
5.6.3	Methods .....	54
5.6.4	Trustworthiness .....	56
6	CLINICAL IMPLICATIONS .....	59
7	FUTURE DIRECTIONS AND RESEARCH .....	61
7.1	Preventive measures.....	61
7.1.1	Exercise interventions .....	61
7.1.2	Intervention targeting single risk factors .....	61
7.2	Suggestions for further research .....	62
8	CONCLUSION.....	63
9	ACKNOWLEDGEMENTS.....	64
10	REFERENCES .....	66

## LIST OF ABBREVIATIONS

ASIA	American Spinal Injury Association
AIS	ASIA Impairment Scale
BBS	Berg Balance Scale
BESTest	Balance Evaluation Systems Test
CI	Confidence interval
FES-I	Fall Efficacy Scale International
ICF	International Classification of Functioning, Disability and Health
ISNCSCI	International Standards for Neurological Classification of Spinal Cord Injury
Karolinska Institutet	KI
Mini-BESTest	Mini Balance Evaluation Systems Test
MnSq	Mean square
OR	Odds ratio
ProFaNe	Prevention of Falls Network Earth (formerly Prevention of Falls Network Europe)
Rehab Station /Spinalis	Rehab Station Stockholm/Spinalis SCI Unit
SCI	Spinal cord injury
SCIM	Spinal Cord Independent Measure
SCIP FALLS Study	Spinal Cord Injury Prevention of Falls Study
SD	Standard deviation
SunRH	Sunnaas Rehabilitation Hospital
TST	Timed Stands Test
TUG	Timed Up and Go test
WISCI	Walking Index for Spinal Cord Injury
10MWT	Ten Metre Walk Test

# 1 INTRODUCTION

A damage of the spinal cord is a devastating event with lifelong consequences. Individuals with incomplete spinal cord injuries (SCI) who are able to walk often have impaired balance control due to reduced sensory and/or motor function. This impaired balance increases the risk of falling and, consequently, fall-related injuries and other adverse outcomes in this population. Due to new demographic trends an increasing number of individuals are at risk of falling due to a higher age at injury, an increasingly long survival into older age and a higher percentage of cervical and incomplete injuries.<sup>1,2</sup>

Falls in individuals with SCI is a fairly new research field, and only a few studies have been carried out in SCI<sup>3-11</sup> or as a part of mixed neurological populations including SCI.<sup>12,13</sup> These studies indicate a high incidence of falls and also give some indications on the factors associated with falls. However, the research findings are inconclusive, and previous studies have been limited by small samples<sup>3,10</sup> and weaknesses and diversity in the study designs<sup>5,6,14,15</sup> as well as in the recruitment processes.<sup>3,5-7,10</sup> To develop preventive strategies it is important to fill in the gap of knowledge and study the incidence of falls and to identify risk factors for falls in this population.

The thesis is part of the Norwegian/Swedish multi-centre study – SCIP FALLS Study (Spinal Cord Injury Prevention of Falls Study), a cooperation between Sunnaas Rehabilitation Hospital (SunRH), Rehab Station Stockholm/Spinalis SCI Unit (Rehab Station/Spinalis) and Karolinska Institutet (KI). The long-term goal of the SCIP FALLS Study is to reduce the risk of falling and fall-related injuries in individuals with SCI as well as to create SCI-specific evidence-based prevention programmes.

This thesis focuses on falls in ambulatory individuals. To illuminate a wide variety of aspects related to falls in this group, the thesis is methodologically divided into three parts: an epidemiological part (Studies I and II), an explorative part (Study III) and a methodological part (Study IV). Within the thesis, the International Classification of Functioning, Disability and Health (ICF) (Figure 1) has been used as a framework to conceptualise impairments, activity limitations, participation restrictions and contextual factors in relation to falls, fall risk and balance impairments in ambulating individuals with SCI.<sup>16</sup>

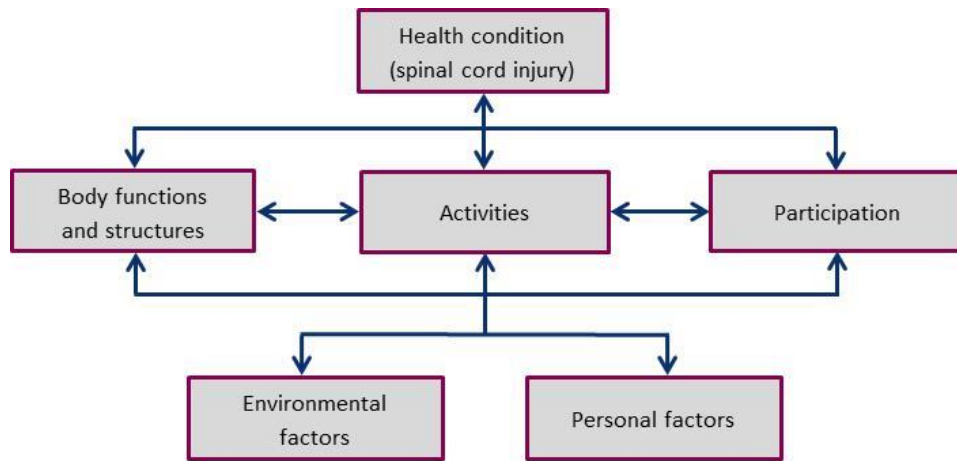


Figure 1. The International Classification of Function, Disability and Health, illustrated by its model <sup>16</sup>.

## 1.1 SPINAL CORD INJURY

### 1.1.1 Definitions

SCI is defined as damage to any part of the spinal cord or nerves within the spinal canal and it can be caused either by a traumatic injury or by a non-traumatic injury. This damage leads to a loss of sensory function and/or a loss of muscle function (paresis) at and below the level of the lesion. The degree of sensory and motor function loss depends on the level and extent of the lesion.<sup>17</sup>

SCI is classified according to the International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI) (Figure 2).<sup>18</sup> Twenty-eight dermatomes are assessed bilaterally using pinprick and light touch sensation, and ten key muscles (5 in the arms and 5 in the legs) are assessed bilaterally with manual muscle testing (scores 0–5) in a supine position. The neurological level is defined as the most caudal segment of the spinal cord with normal sensory and motor function. The extent of injury is defined according to the AIS (Table 1).<sup>19</sup>

*Tetraplegia* refers to a loss of motor and/or sensory function due to damage to the cervical spinal cord segments, which results in impairments in all four extremities as well as in the trunk and pelvic organs. *Paraplegia* refers to a loss of motor and/or sensory function due to damage to spinal cord segments in the thoracic, lumbar or sacral regions, including the conus medullaris

**INTERNATIONAL STANDARDS FOR NEUROLOGICAL  
CLASSIFICATION OF SPINAL CORD INJURY  
(ISNCSCI)**

Patient Name \_\_\_\_\_ Date/Time of Exam \_\_\_\_\_  
 Examiner Name \_\_\_\_\_ Signature \_\_\_\_\_

### RIGHT

**MOTOR KEY MUSCLES**

**UER** (Upper Extremity Right)

Elbow flexors C5

Wrist extensors C6

Elbow extensors C7

Finger flexors C8

Finger abductors (little finger) T1

**LER** (Lower Extremity Right)

Hip flexors L2

Knee extensors L3

Ankle dorsiflexors L4

Long toe extensors L5

Ankle plantar flexors S1

(VAC) Voluntary anal contraction (Yes/No) ☐

**KEY SENSORY POINTS**

Light Touch (LTR)

Pin Prick (PPR)

C2		
C3		
C4		
C5		
C6		
C7		
C8		
T1		
T2		
T3		
T4		
T5		
T6		
T7		
T8		
T9		
T10		
T11		
T12		
L1		
L2		
L3		
L4		
L5		
S1		
S2		
S3		
S4-5		

### LEFT

**MOTOR KEY MUSCLES**

**UEL** (Upper Extremity Left)

Elbow flexors C5

Wrist extensors C6

Elbow extensors C7

Finger flexors C8

Finger abductors (little finger) T1

**LEL** (Lower Extremity Left)

Hip flexors L2

Knee extensors L3

Ankle dorsiflexors L4

Long toe extensors L5

Ankle plantar flexors S1

(DAP) Deep anal pressure (Yes/No) ☐

**KEY SENSORY POINTS**

Light Touch (LTL)

Pin Prick (PPL)

C2		
C3		
C4		
C5		
C6		
C7		
C8		
T1		
T2		
T3		
T4		
T5		
T6		
T7		
T8		
T9		
T10		
T11		
T12		
L1		
L2		
L3		
L4		
L5		
S1		
S2		
S3		
S4-5		

**RIGHT TOTALS (MAXIMUM)** (50) (56) (56)

**LEFT TOTALS (MAXIMUM)** (56) (56) (50)

**MOTOR SUBSCORES**

UER  + UEL  = UEMS TOTAL  (MAX (25) (25) (50))

LER  + LEL  = LEMS TOTAL  (MAX (25) (25) (50))

**SENSORY SUBSCORES**

LTR  + LTL  = LT TOTAL  (MAX (56) (56) (112))

PPR  + PPL  = PP TOTAL  (MAX (56) (56) (112))

**NEUROLOGICAL LEVELS**

Steps 1-5 for classification as on reverse

1. SENSORY  R  L

2. MOTOR  R  L

3. NEUROLOGICAL LEVEL OF INJURY (NLI)

4. COMPLETE OR INCOMPLETE?

Incomplete = Any sensory or motor function in S4-5

5. ASIA IMPAIRMENT SCALE (AIS)

**ZONE OF PARTIAL PRESERVATION**

(In complete injuries only)

Most caudal level with any innervation

SENSORY  R  L

MOTOR  R  L

This form may be copied freely but should not be altered without permission from the American Spinal Injury Association. REV 02/13

Figure 2. The International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI) scoring sheet.<sup>20</sup>

Table 1. Classification of extent of injury (complete versus incomplete) according to The American Spinal Injury Association Impairment Scale (ASIA impairment scale [AIS]).<sup>18</sup>

AIS A – Complete	No sensory or motor function is preserved in the sacral segments S4-5.
AIS B – Incomplete	Sensory but not motor function is preserved below the neurological level and includes the sacral segments S4-5 (light touch or pin prick at S4-5 or deep anal pressure) AND no motor function is preserved more than three levels below the motor level on either side of the body.
AIS C – Incomplete	Motor function is preserved below the neurological level, and more than half of key muscle functions below the neurological level of injury (NLI) have a muscle grade less than 3 (Grades 0-2).
AIS D – Incomplete	Motor function is preserved below the neurological level, and <u>at least half</u> (half or more) of key muscle functions below the NLI have a muscle grade $\geq 3$ .
AIS E – Normal	If sensation and motor function as tested with the ISNCSCI are graded as normal in all segments, and the patient had prior deficits, then the AIS grade is E. Someone without an initial SCI does not receive an AIS grade.

3

and cauda equina. The arms are spared, but the legs, trunk and pelvic organs may be affected, based on the level of injury.<sup>18</sup>

Depending on the neurological level and extent of the injury, many individuals with SCI retain the ability to walk. In general, individuals classified as AIS D are ambulatory, whereas individuals classified as AIS A–C are confined to wheelchairs. In this thesis, the participants were classified as ambulatory if they reported walking at least 75 per cent of the time to meet their mobility needs. Likewise, they were classified as able to walk if they could walk at least 10 metres independently with or without walking aids. Individuals were classified as wheelchair users if they reported using a wheelchair at least 75 per cent of the time to meet their mobility needs.

### **1.1.2 Aetiology**

Causes of injury are classified into the following categories:

1. Sport and leisure activities
2. Assaults
3. Transport activities
4. Falls
5. Other traumatic causes
6. Non-traumatic causes
7. Unknown

As overlap can occur between categories, they are ranked in order of priority.<sup>21</sup> Traumatic SCI, which is the group studied in this thesis, comprises the first five categories. In Norway and Sweden, accidental falls are currently the primary cause of injury, followed by transport accidents.<sup>22,23</sup>

This thesis concerns individuals with chronic ( $\geq 1$  year post injury) traumatic SCI, hereafter referred to as SCI.

### **1.1.3 Incidence and prevalence of SCI**

There is a significant variation in and much uncertainty regarding the incidence and prevalence of SCI worldwide.<sup>24</sup> The incidence has been estimated as 14–20 injuries per million inhabitants per year in Norway and 19.5 per million/year in Sweden.<sup>23,25,26</sup> In a study of two counties in Western Norway, the crude prevalence was estimated to be 365 persons/million inhabitants, and The Stockholm Spinal Cord Injury Study in 1995 reported a prevalence rate of 223 persons/million in Sweden.<sup>25,26</sup> Similar rates are found in other Western countries.<sup>1,2,27,28</sup>



#### **1.1.4 Demographic characteristics in Western countries**

SCI mostly affects men, who account for approximately 75–80 per cent of all cases in Norway and Sweden.<sup>23,29,30</sup> Incidence rates peak for individuals in their late teens, and in many countries there is a second peak in the elderly.<sup>1,31</sup> The mean age at injury in Norway and Sweden is presently just over 45 years,<sup>23,30,32</sup> which is higher than in previous decades.<sup>23,32,34</sup>

Due to preventive measures and better intensive care, the number of individuals with complete lesions has decreased, and approximately half are currently diagnosed with motor incomplete injuries.<sup>30,32,33</sup>

#### **1.1.5 Rehabilitation and lifelong follow-up**

After initial treatment in acute hospitals, patients are transferred for rehabilitation. The SCI rehabilitation programs offered by SunRH and Rehab Station /Spinalis are comparable, and the main rehabilitation goal for individuals is to optimise everyday life activities and participation in society. This includes improving physical function and providing compensatory means when necessary. The length of in-hospital rehabilitation depends on a variety of individual factors, such as the level and extent of injury as well as the person's age and rehabilitation progress, but it is tied to systemic factors such as the economy and politics related to health. However, improvements in physical function continue for an extended period of time after discharge due to improvements in neuromuscular function as well as improvements resulting from exercise.

Because SCI is a rare condition and entails lifelong consequences, life-long follow-up programmes are offered to all individuals within the catchments areas of SunRH and RSS/Spinalis. Hence, this population is accessible for individual interventions initiated by SCI units, which may be of value when targeting falls.

#### **1.1.6 The importance of walking**

Not surprisingly, regaining or improving walking ability is a main rehabilitation goal for the majority of patients with SCI, especially for individuals with incomplete lesions. Walking and 'standing on your own feet' symbolise a whole set of moral characteristics, such as rectitude, dignity, autonomy and 'standing by' one's convictions.<sup>34</sup> Thus, the ability to stand and walk has great symbolic value in terms of being a 'normal' human being. An investigation of the preferences of individuals with SCI revealed that walking was viewed as important as bladder and bowel control, regardless of the amount of time after injury.<sup>19</sup> In addition, the decreased ability to walk or move was reported to be one of the most challenging consequences of SCI.

## 1.2 FALLS AND ADVERSE CONSEQUENCES OF FALLS

### 1.2.1 Definitions

For the purpose of the SCIP FALLS Study, we have used the European Fall-Prevention Network Earth (ProFaNE) definition of a fall: ‘an unexpected event in which the participants come to rest on the ground, floor, or lower level’.<sup>35</sup> Recurrent falls were defined as more than two falls per year.

Fall-related injuries were classified according to the taxonomy suggested by Schwenk as follows:<sup>36</sup>

- *serious*: medically recorded fracture, head or internal injury requiring accident and emergency or inpatient treatment
- *moderate*: wounds, bruises, sprains, cuts requiring a medical/health professional examination, such as physical examination, x-ray, sutures
- *minor*: minor bruises or abrasions not requiring professional health assistance; reduction in physical function for at least three days
- *no injury*: no physical injury detected

### 1.2.2 Falls

Falls are common in the SCI population.<sup>3,5,7,10-13,37</sup> Most studies have focused on falls in ambulatory individuals with incomplete SCI, with reported incidences ranging from 31 to 75 per cent per 6–12 months.<sup>3-7,10</sup> In wheelchair users with SCI, the fall incidence was reported to be 31 per cent in one study.<sup>11</sup>

Descriptions of fall events among ambulatory individuals are mostly lacking in the literature. Two studies found that most falls occurred when walking within the house or its immediate surroundings in the daytime (5 am to 5 pm).<sup>3,7</sup> The participants indicated muscle weakness, environmental hazards and slippery floor as the major causes of falls.

### 1.2.3 Fall-related injuries

In a retrospective study focusing on fall-related injuries in ambulatory individuals, 20 per cent reported having an injury serious enough to seek medical care.<sup>15</sup> Other studies have reported lower incidence rates ranging between 2 and 14 per cent.<sup>3,4,7,10,14</sup> Reported fracture incidences vary between 1 and 18 per cent.<sup>3,4,7,10</sup>

#### **1.2.4 Fall-related psychological aspects**

In addition to physical consequences, falls can be associated with various psychological implications that compromise quality of life, particularly in the elderly.<sup>38</sup> However, the relation between falls and psychological concerns remains unclear.<sup>39,40</sup> To our knowledge, fall-related psychological aspects have only been reported in three studies.<sup>4,7,9</sup> Two studies showed that a fear of falling increased the odds of falling,<sup>4,7</sup> and one study found that individuals who limited their participation in community activities because of a fear of falling were more likely to experience falls.<sup>4</sup>

Fall-related psychological aspects is an umbrella term for several constructs, including fear of falling, fall-related self-efficacy, balance confidence and outcome expectancy as well as concerns about falling.<sup>41,42</sup> Two constructs, fear of falling and concerns about falling, are used in this thesis.

Fear of falling has been defined as ‘a lasting concern about falling that leads to an individual avoiding activities that he/she remains capable of performing.’<sup>43</sup> However, it can be difficult to differentiate this avoidance from normal avoidance of unsafe activities. The concept includes both emotional (i.e. anxiety) and behavioural aspects (i.e. avoidance of activity).<sup>44</sup> Measures of fear of falling include closed-ended questions such as ‘In general, are you afraid of falling?’ which have been criticised for a lack of sensitivity.<sup>38,45</sup>

The Fall Efficacy Scale International (FES-I) is one of several tools measuring concerns about falling.<sup>41,46</sup> It is a widely spread instrument and has been acknowledged as the ‘gold standard’ with good psychometric properties for measuring concerns about falling in everyday activities in older adults.<sup>44,47</sup> The FES-I was developed from an instrument measuring fall-related self-efficacy (Fall Efficacy Scale) but did not change the name, which has led to some confusion as to which construct it measures.<sup>45</sup>

Fear of falling and concerns about falling will hereafter be referred to as fall-related concerns when discussed together.

#### **1.2.5 Risk factors for falls and fall-related injuries**

Risk factors for falls in ambulatory individuals with SCI are inconsistently identified. This is partly due to few studies with relatively small samples, which have used weak study designs and statistical methods to identify the risk factors. Paraplegia or higher level of functional independence, male gender, previous falls, fewer years post-injury, pain, higher alcohol consumption and a shorter wheelbase have been reported as factors associated with falls in wheelchair users.<sup>11,46</sup> For ambulatory individuals, risk factors include level of physical

function,<sup>6-8,15</sup> exercise level,<sup>5,7,37</sup> comorbidity and physical health<sup>4,14,37</sup> as well as fear of falling.<sup>4,7</sup>

Little is known about the risk factors for injurious falls. In a study of 759 adults aging with SCI,<sup>14</sup> injurious falls serious enough to receive medical care were associated with equal time spent walking and wheeling and the use of prescription medication.

In some studies, participants have been asked which factors they perceived as contributing to their falls. The three most important factors mentioned were decreased strength in the trunk and lower extremities, loss of balance and environmental hazards.<sup>3,5,48</sup> Alcohol and prescription medications were not perceived to be related to falls in the study of Brotherton et al.<sup>5</sup>

## **1.3 BALANCE CONTROL**

### **1.3.1 Definition**

Balance control is defined as the ability to maintain an appropriate relationship between the body segments and between the body and the environment when performing a functional task. A complex interaction between motor (including muscle synergies), sensory (including visual, vestibular and somatosensory systems) and cognitive processes is necessary to control the body in space.<sup>49</sup>

There are essentially three types of balance control: steady state, reactive and proactive or anticipatory balance. Steady state balance is defined as the ability to control the centre of mass relative to the base of support in fairly predictable and non-changing conditions. Reactive balance control is the ability to recover a stable position following an unexpected perturbation, whereas anticipatory balance control is the ability to activate muscles for balance control in advance of potentially destabilising voluntary movements.<sup>49</sup>

### **1.3.2 Balance control in SCI**

Balance control is the basis for an individual's ability to move and function independently and a prerequisite for rehabilitation of upright movements of the body involving the trunk.<sup>50</sup> Due to a partial or total loss of motor function and sensory input below the level of lesion, most individuals with SCI experience impaired balance control, which in turn increases the risk of falling. The degree of balance impairment depends on the level and extent of the lesion and because of the great variation of impairments in this group, there is also a wide range in terms of balance control; from the inability to sit independently to minimal impact on upright function.

### 1.3.3 Assessment of balance control

The assessment of balance control during rehabilitation as well as from a lifelong perspective is important as assessment may identify disorders in the different systems involved in balance control. This gives an indication of how to target balance problems. Repeated testing can provide knowledge about outcomes after interventions, such as balance training.

The Berg Balance Scale (BBS) was originally developed to assess balance control and to predict falls in elderly.<sup>51</sup> It is currently the balance test recommended for clinical use in SCI.<sup>52,53</sup> According to the developers, BBS assesses functional balance through tasks challenging balance control in sitting and standing. It tests static and proactive balance. The scale has several constraints, including a ceiling effect and a relatively low responsiveness, which limit its utility in ambulatory individuals with chronic SCI. Additionally, BBS has not been able to predict falls in SCI populations.<sup>10,54-58</sup> These limitations lead to the following question: Is there another balance test with better clinical and psychometric properties that is more appropriate for use in the SCI population?

The Balance Evaluation Systems Test (BESTest) is a theory-based comprehensive clinical balance test developed to identify the postural control systems causing balance impairments.<sup>50</sup> The test breaks down balance control into six distinct parts based on the different systems underlying balance control: biomechanical restraints, stability limits, anticipatory and reactive balance reactions, sensory orientation and stability in gait.<sup>50,59,60</sup> It assesses dynamic balance through tasks related to dynamic body stability, transfers, varying conditions during gait, varying support surfaces and visual conditions when standing.<sup>61</sup> However, due to the extensive length of this test, a shorter version, the Mini Balance Evaluation Systems Test (Mini-BESTest) was derived through factor analysis and Rasch analysis.<sup>59</sup> It covers four of the six original underlying systems: anticipatory and reactive balance reactions, sensory orientation and stability in gait. The Mini-BESTest has been found to have good concurrent validity for individuals with neurological disorders such as stroke and Parkinson's disease (PD).<sup>62,63</sup> Moreover, it has a reasonably accurate predictive validity in identifying future recurrent fallers among individuals with PD, especially during the first six months following assessment.<sup>64</sup> The psychometric properties of the Mini-BESTest have not been tested in the ambulatory SCI population.

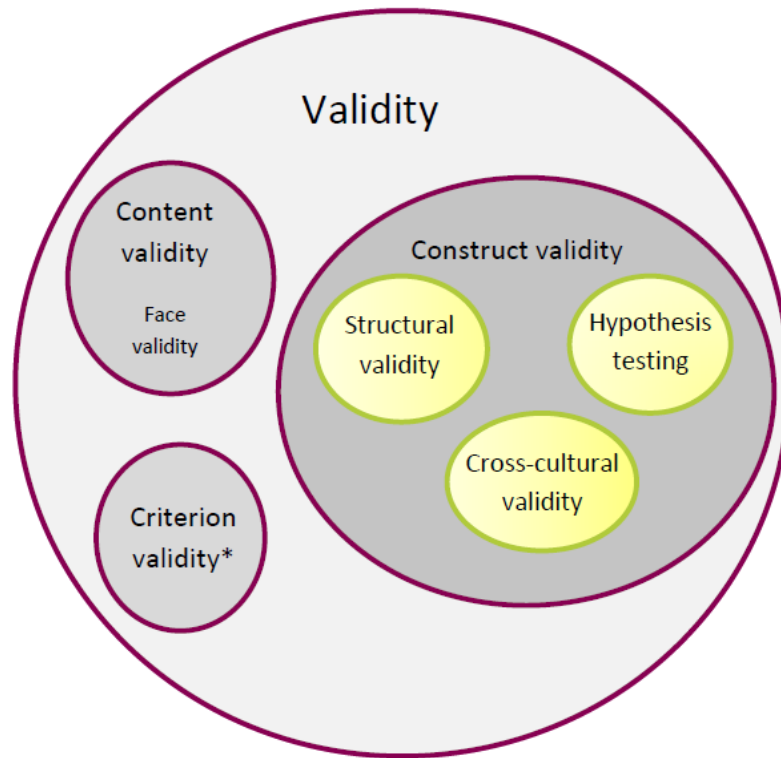


Figure 3. The concept of validity as defined by the COSMIN panel.<sup>65</sup>

\*Can be subdivided in concurrent validity and predictive validity.

## 1.4 MEASUREMENT PROPERTIES OF ASSESSMENT TOOLS

Assessment tools are central in clinical practice and research. In physiotherapy practice, they form a basis for evaluation of the patient status and treatment effects. Reliability, responsiveness and validity are all aspects that need to be considered before using an instrument.

Validity is defined by the COSMIN (COnsensus-based Standards for the Selection of health Measurement Instruments) panel as ‘the degree to which an instrument truly measures the construct(s) it purports to measure.’<sup>65</sup> The panel has distinguished three types of validity (Figure 3):<sup>66</sup>

- Content validity focuses on whether the content of the instruments corresponds with the construct measured.
- Criterion validity refers to how well the scores on instruments correspond to scores on a gold standard.
- Construct validity is used when a gold standard is lacking and refers to whether the instruments provide the expected scores based on existing knowledge about the construct.

## 1.5 RATIONALE FOR THIS THESIS

The demographic trends showing higher age at injury, a slightly higher proportion of women, a higher percentage of cervical and incomplete injuries (AIS C and D) as well as increased long term survival, lead to more individuals being at risk of falling. Falls may have adverse implications such as injuries adding to disability. In addition, the increasing percentage of fall-induced SCI<sup>1,2,28,30</sup> as well as falls post-injury may lead to a fear of falling accompanied by self-imposed restrictions on activities to avoid falls. Attempting to manage these population changes raises new clinical questions.

At present, there is little research on falls and fall risk in the SCI population. This gap of knowledge, as well as the increasing clinical challenges falls and fall risk pose during rehabilitation and follow-up, necessitate research on falls and fall risk in this population. There is a need to further quantify the problem, identify risk factors and highlight the perceptions of the individuals themselves regarding falls and fall risk as a basis for developing preventive strategies.

We hypothesise that individuals with chronic SCI in Norway and Sweden have a high risk of falling and sustaining fall-related injuries, and that ambulating individuals have a higher risk of falling compared to wheelchair users. We presume that each individual has unique experiences and perceptions on falls and fall risk. Furthermore, we hypothesise that both the BBS and the Mini-BESTest are valid tests for balance control in ambulatory individuals with SCI, and that the Mini-BESTest lacks a ceiling effect and can discriminate recurrent fallers from low frequency fallers.





## 2 AIMS

The overall aim of this thesis was to study the incidence of and identify the risk factors for recurrent falls in ambulatory individuals with SCI. Each study, with its specific aims, is listed below.

The studies included in this thesis covered the following specific aims:

- Study I*      To identify factors associated with falling in individuals with SCI.
- Study II*      To report the 12-month incidence rates of falls and injurious falls and to develop prediction models for recurrent falls (>2/year) and injurious falls in a representative cohort of ambulatory individuals with SCI.
- Study III*      To explore and describe experiences and perceptions of falls, risk of falling and fall-related consequences in ambulatory individuals with SCI.
- Study IV*      To validate and compare the psychometric properties of the BBS and the Mini-BESTest in individuals with chronic SCI



### 3 MATERIAL AND METHODS

#### 3.1 DESIGN

Four studies with different designs are included in this thesis (Figure 4). **Study I** is a cross-sectional multi-centre study of falls; **Study II** is a 12-month prospective multi-centre study of falls; **Study III** is a qualitative study on experiences and perceptions of falls and risk of falling; and **Study IV** is a methodological study comparing two clinical balance assessment instruments.

<p style="text-align: center;"><b>Study I</b></p> <p><b>Design</b> Cross sectional multi-centre</p> <p><b>Setting and sample</b> 224 individuals from Norway and Sweden (ambulatory individuals and wheelchair users)</p> <p><b>Outcome measures</b> Fall frequency, retrospectively Associated factors with recurrent (&gt;2) falls</p> <p><b>Analysis</b> Multiple logistic regression</p>	<p style="text-align: center;"><b>Study II</b></p> <p><b>Design</b> Longitudinal observational multi-centre</p> <p><b>Setting and sample</b> 68 ambulatory individuals from Norway and Sweden</p> <p><b>Outcome measures</b> Fall and injury frequencies. Predictors for recurrent falls (&gt;2) and injurious fall</p> <p><b>Analysis:</b> Multiple logistic regression</p>
<p style="text-align: center;"><b>Study III</b></p> <p><b>Design</b> Explorative cross-sectional</p> <p><b>Setting and sample</b> 15 ambulatory individuals from Norway</p> <p><b>Outcome measures</b> Experiences and perceptions of falls and risk of falling</p> <p><b>Analysis</b> Interpretive content analysis</p>	<p style="text-align: center;"><b>Study IV</b></p> <p><b>Design</b> Methodological cross-sectional</p> <p><b>Setting and sample</b> 46 individuals from Norway able to walk</p> <p><b>Outcome measures</b> Berg Balance Scale and Mini-BESTest</p> <p><b>Analysis</b> Classical test theory and item response theory</p>

Figure 4. Overview of designs, settings and samples, outcome measures and the main analysis methods of the studies included in this thesis.

## **3.2 ETHICAL CONSIDERATIONS**

The studies were non-therapeutic, and consequently, participants would not benefit directly from participation, which may have influenced the inclusion rate. Ethical considerations were addressed and appropriate measures were taken concerning the recruitment process, the increased risk of falling and the risk of exhaustion during the data collection. Procedures for handling any medical or social problems discovered during follow-up were planned.

The participants provided informed consent after receiving written and oral information. The consent could be withdrawn at any time without justification.

The study was approved by the Regional Ethics Committee for Medical Research Ethics in South East Norway May 2012, August 2012 and March 2013 (Dnr: 2012/531) and by the Local Ethics Committee in Stockholm, Sweden (Dnr: 2012/830-31/2, 2013/391-32, 2014/364-32).

## **3.3 PARTICIPANTS**

### **3.3.1 Inclusion and exclusion criteria**

For all studies, the general inclusion criteria were as follows: traumatic complete or incomplete SCI, a minimum of one year post-injury, age 18 years or older and able to cooperate and understand Norwegian or Swedish in speech and writing. Individuals with complete motor lesions above C5 (AIS A and B) or lesions below L5 as well as individuals with normal sensory and motor functions (AIS E) were excluded. Due to the different aims of the studies, the following additional specific criteria were used:

- Study I; being able to ambulate or propel independently for a minimum of 10 metres with or without assistive devices or manual or electric wheelchair.
- Study II; being ambulatory  $\geq 75$  per cent of the time to meet mobility needs.
- Study III; being ambulatory  $\geq 75$  per cent of the time to meet mobility needs and experiencing at least one fall in the previous year.
- Study IV; being able to walk independently for a minimum of 10 metres with or without assistive devices.

### 3.3.2 Sample sizes

Studies I and II were planned to include 200 subjects. As distinct numbers in this area are scarce, we estimated that we would have approximately 50 per cent ambulatory individuals and 50 per cent wheelchair users. The sample size equals 12–15 per cent of the patients in the SCI database at the two SCI units. As shown in the introduction, with a fall incidence of 70 per cent in ambulatory and 30 per cent in wheelchair-using individuals, 200 subjects would render 100 persons with falls, allowing for a maximum of 10 variables in the final prediction model for the total sample<sup>67</sup>. Due to the results in Study I, where ambulatory and wheelchair users were shown to be two distinct subgroups, the sample was split for the prospective study (Study II). Although 224 individuals were included, only 73 (33%) were classified as ambulatory, which weakens the power of the final multiple logistic regression analysis of this subgroup.

For Study III, the sample size was based on similar qualitative studies.

The sample in Study IV consisted of all Norwegian participants in the SCIP FALLS Study who were able to walk 10 metres and had completed a Mini-BESTest.

### 3.3.3 Recruitment and inclusion

Potential participants were consecutively identified and selected when attending their regular in- (Norway) or out-patient (Sweden) follow-up programmes at least one year or more post-injury. Of 270 eligible patients, a total of 224 individuals were recruited; 106 from SunRH (Health Region South-East) from February 2013 to March 2014, and 118 from Rehab Station /Spinalis (the greater Stockholm County) from April 2013 to May 2014. Five additional individuals were recruited for the sample in Study III from March to April 2014 in connection with their regular follow-up program at SunRH. A flowchart of the recruitment processes is shown in Figure 5.



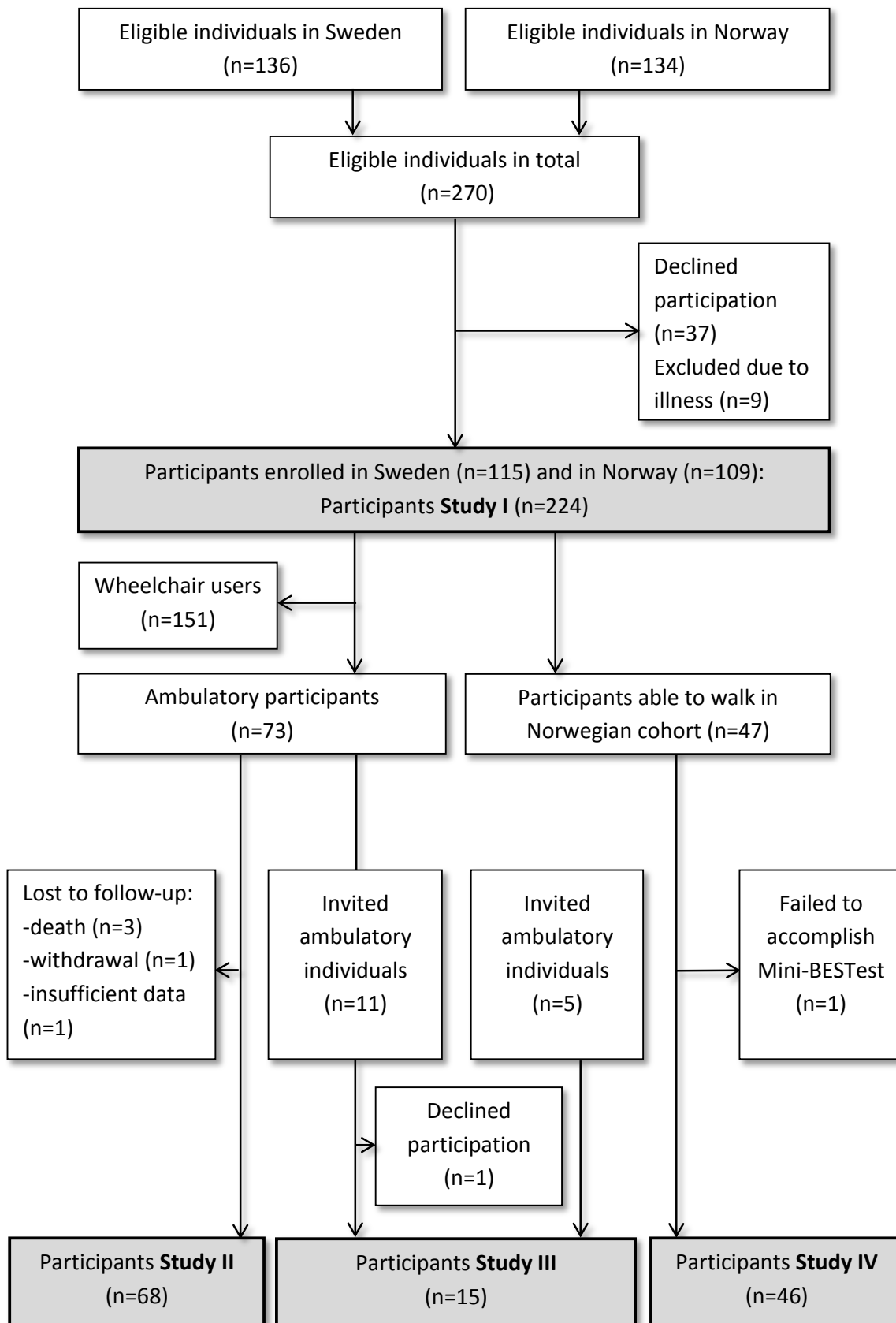


Figure 5. Flowchart illustrating the recruitment process and sample sizes for all studies, as well as reasons for exclusion (studies I and IV) and drop-outs (studies II and III).

### 3.4 DATA COLLECTION

For studies I, II and IV, all baseline and fall data were collected by the author at SunRH and by fellow Ph.D. candidate Emelie Butler Forslund at Rehab Station/Spinalis. To ensure similar conditions during baseline data collection, the time frame was set according to the time available for outpatient consultations. In addition, the investigators discussed and practiced the baseline assessments together before inclusion. All tests were done in the same order. Telephone interviews and fall data collection were conducted with structured forms.

#### 3.4.1 Outcome measures

Due to the explorative nature of the SCIP FALLS Study, a variety of data were gathered at baseline. The data collection consisted of structured interviews, questionnaires and clinical tests as well as data from medical records. Table 2 gives an overview of the variables and instruments collected in the respective studies presented according to the framework of the ICF.<sup>16</sup>

Valid and reliable assessment tools for the SCI population were chosen as far as possible. However, since this is a low frequency diagnosis, some instruments have not yet been validated for this population.

##### 3.4.1.1 Falls and injurious falls

At baseline, participants were asked if they had fallen in the previous year, and if so, how many times they had fallen. Falls were then monitored for 12 months. An automatic short message service (SMS)<sup>68</sup> was posted every second week asking if the participant had fallen. The reply alternatives were ‘yes’ or ‘no’. If the participant answered ‘yes’, the number of falls and fall-related injuries as well as the severity of the injuries and the perceived causes of the falls were registered and classified during a telephone interview. In the event there was no reply to the SMS, an automatic SMS-reminder was sent after two days. If this was not answered either, the participant was contacted by telephone. In addition, all participants were contacted every four months to ensure compliance (Figure 6).

##### 3.4.1.2 Fall-related psychological aspects

The FES-I,<sup>41</sup> Spinal Cord Injury Falls Concern Scale (SCI-FCS)<sup>69</sup> and the single-item question on fear of falling,<sup>38</sup> were used to capture the participants’ concerns about falling.

The FES-I, originally developed for the elderly, is a self-report task-specific scale measuring an ambulating individual’s concerns about falling in 16 everyday activities. Each item is scored on a

Figure 6. Illustration of design in Study II.



four-point ordinal scale (1 = not at all concerned, 2 = somewhat, 3 = fairly, and 4 = very concerned), the sum score being 16–64 points. The scale has been translated and is valid for older persons in Norway.<sup>70</sup> No validation has been done in the SCI population. For Study II, the questionnaire was answered twice, at baseline and at 12-month follow-ups (by mail).

The SCI-FCS<sup>69</sup> is a 16-item scale based on the FES-I, and it has corresponding grading and sum score, addressing concerns about falling in 16 activities of daily living associated with falling that are specific to wheelchair-dependent individuals with SCI. It has been translated to Norwegian and Swedish, and it has been found to be a valid and reliable measure for these populations.<sup>71,72</sup>

Fear of falling was investigated with the question ‘In general, are you afraid of falling?’, with the answering options ‘not at all afraid’, ‘a little afraid’, ‘a bit afraid’, and ‘very afraid’.<sup>38,73</sup> In Study I the answering options were dichotomised in a fear group comprising ‘quite a bit afraid’ and ‘very afraid’ versus a no-fear group comprising ‘not at all afraid’ and ‘a little afraid’. In order to compare our findings in Study II, with those in the prospective study of Phonthee et al.<sup>7</sup> who reported on the fear of falling in ambulatory individuals with SCI, the answering options were dichotomized in ‘not at all afraid’ or afraid of falling (containing the remaining three answering options).

#### 3.4.1.3 Balance control

Balance control was assessed with the BBS, a valid, reliable and currently recommended balance test for the SCI population.<sup>10,56</sup> It consists of 14 items that evaluate the ability to maintain a position and to adjust to voluntary movements. Each item is scored on an ordinal scale ranging from 0 to 4, with a total score ranging from 0 to 56 points. No assistive devices are permitted during testing. Items were tested in the order of the testing scheme.

The *Mini-BESTest* was applied in Study IV. It is a relatively new test, based on former balance tests, and aims to help physiotherapists to identify the underlying postural control systems responsible for poor functional balance.<sup>50,59,74</sup> Fourteen items cover the subsystems’ anticipatory postural adjustments, postural responses, sensory orientation and balance during gait. Each item is scored on an ordinal scale ranging from 0 to 2, with a sum score ranging from 0 to 28 points. For item 3 (stand on one leg) and item 6 (compensatory stepping correction in lateral direction), both sides are tested, but only the lower results are recorded as required.<sup>60</sup> Lower limb orthopaedic aids are permitted during testing if necessary, but this automatically results in a lower score according to the test manual.<sup>75</sup>

Table 2. Overview of primary and secondary outcome variables collected in the SCIP FALLS Study\* (outcome properties, outcome measures and units) sorted according to International Classification of Functioning, Disability and Health (ICF).<sup>16</sup>

Outcome property/quality	Measurement instrument (reference)	Unit	Study I	Study II	Study III	Study IV
<b><u>PRIMARY</u></b>						
Falls	Falls, retrospective	Number	x	x	x	
	Falls, prospective	Number			x	x
Injurious falls	Fall-related injuries	Number			x	
Balance	Berg Balance Scale <sup>10</sup>	Sum score 0-56	x	x		x
	Mini-BESTest <sup>59</sup>	Sum score 0-28				x
<b><u>SECONDARY</u></b>						
<b><i>Personal factors</i></b>						
Socio-demographic	Age, duration of SCI	Years	x	x	x	x
	Gender		x	x	x	x
	Education-level	Classification 1-6	x	x	x	
	Work /studies	Per cent of occupation	x	x		
Fall-related psychological aspects	Spinal Cord Injury Falls Concern Scale <sup>69</sup>		x			
	Falls Efficacy Scale – International <sup>41</sup>		x	x		x
	Fear of falling <sup>38,73</sup>	Classification 1-4	x	x	x	x
Risk willingness	One question ‘I like to take chances’ <sup>76</sup>	Yes/no	x	x	x	x
Quality of life	Euroqol Visual Analogue Scale (EQ VAS) <sup>77</sup>	Rating 0-100%	x			
	International SCI Quality of Life Basic Dataset <sup>78</sup>	Rating 0-10	x	x		x
<b><i>Body function and structure</i></b>						
SCI specific characteristics	Injury aetiology <sup>21</sup>	Classification 1-5	x	x	x	x
	Injury level (ISNCSCI)** <sup>18</sup>	Classification 1-4	x	x	x	x

	AIS-score <sup>18</sup>	Classification A-E	x	x	x	x
SCI complications	Spinal Cord Injury Secondary Conditions Scale <sup>79</sup>	Sum score 0-48	x	x		x
Spasticity	Spasm Frequency and Spasm Severity <sup>80</sup>	Classification 1-4 and 1-3	x	x	x	x
Muscle strength	Timed stands test <sup>81</sup>	Seconds	x	x		x
Fatigue	Fatigue Severity Scale (FSS) <sup>82</sup>	Sum score 9-63	x	x		
Anxiety and Depression	Hospital Anxiety and Depression Scale (HADS) <sup>83</sup>	Sum score 0-22 and 0-22	x	x		
<b><i>Activity and participation</i></b>						
Functional status	Spinal Cord Independence Measure, version III (SCIM), mobility items <sup>84</sup>	Sum score 0-40	x	x		x
	Percentage wheelchair/ambulation	Classification 1-5	x	x		x
	Hoffer Ambulation Index <sup>85</sup> (modified)	Classification (1a/1b-4)		x		
	Walking Index for Spinal Cord Injury, version II <sup>86</sup>	Classification 0-20	x	x		x
	Ability to get up from ground by oneself	Yes/no	x	x	x	
	Number of sitting transfers per day	Classification (2-4/5-14/>15)	x			
Walking skills	10m Walk Test (10MWT) <sup>87</sup>	Seconds	x	x		x
	Timed up and go (TUG) <sup>88</sup>	Seconds	x	x		x
Wheelchair skills	Timed 200m wheelchair pushing	Seconds	x			
	Negotiate 10 cm high curb	Yes/no	x			
Physical activity	Leisure-time activity past year <sup>89</sup>	Classification 1-4	x	x	x	x
<b><i>Environmental factors</i></b>						
Aids	Available technical and orthopaedic aids	Descriptive			x	
	Preferred mobility aid indoors and outdoors	Descriptive	x	x		

\*Spinal Cord Injury Prevention of Falls Study

\*\*International Standards for Neurological Classification of Spinal Cord Injury

#### 3.4.1.4 Risk-taking behavior and alcohol intake

Risk-taking behaviour is a common cause of SCI and for subsequent injuries post-injury,<sup>90</sup> and it may also affect fall rates. Originally, we planned on using the Sensation Seeking Scale<sup>91</sup> to explore this issue. However, we did not get the ethical permission as some questions in the questionnaire were not considered necessary and appropriate to fulfil the aims of the study and also could be perceived as offensive. Therefore, risk willingness was assessed with three questions according to Sussman et al.<sup>76</sup> In the analysis we only used the one question that seemed most relevant for the participants in this study: ‘I like to take chances’, with the alternative answers yes or no.

Alcohol intake may reduce balance control and thus increase the risk of falling. Participants were asked to answer a binary yes/no question about their weekly alcohol consumption according to levels identified by the World Health Organization and adapted in Norway and Sweden: ‘If you drink alcohol, do you drink more than 9 (women)/14 (men) standardised units of alcohol per week?’<sup>92</sup>

#### 3.4.1.5 Quality of life

Quality of life was assessed with two measures: The generic *Euroqol Visual Analogue Scale*<sup>77</sup> was used for scoring the current health-related quality of life. The SCI specific *International SCI Quality of Life Basic Data Set*<sup>78</sup> has good validity<sup>93</sup> and consists of three variables, which the individual uses to rate his or her satisfaction in regard to general quality of life, physical health and psychological health. The variables are rated on a scale ranging from 0 (completely dissatisfied) to 10 (completely satisfied).

#### 3.4.1.6 SCI specific characteristics

Level and extent of the SCI was classified according to International Standards for Neurological classification of Spinal Cord Injury as described in the introduction.<sup>18</sup>

#### 3.4.1.7 Secondary conditions

An SCI is often followed by secondary conditions, which may influence function and cause falls directly or indirectly. *The Spinal Cord Injury - Secondary Conditions Scale*<sup>79</sup> is a valid, although not widely used, self-reported questionnaire targeting conditions that indirectly or directly influence health or function. It covers problems related to skin, musculoskeletal, pain and cardiovascular disease. It consists of 16 health problem areas scored on an ordinal scale: 0 = not experienced in the last 3 months, 1 = mild or infrequent problem, 2 = moderate or occasional

problem and 3= significant or chronic problem. Total scores range from 0 to 48. In this thesis, only questions on pain and spasticity have been used.

Spasticity was assessed with the self-rating Spasm frequency and Spasm severity Scales as well as Interference with Function, scales adapted for individuals with SCI.<sup>80</sup> Spasm frequency is rated on an ordinal scale from 0 to 4 where 0 = no spasms and 4 = spontaneous spasms occurring more than ten times per hour. Spasm severity is rated as mild, moderate or severe. Interference with function is rated as does not interfere, makes function difficult or prevents function.

Fatigue was assessed with the questionnaire the Fatigue severity Scale<sup>82</sup> (FSS). The scale measures effect of fatigue on function. Nine statements are scored on a 7-point ordinal scale ranging from 1 (strongly disagree) to 7 strongly agree to the questions with sum scores ranging from 9 to 49. It has been validated for individuals with complete SCI.<sup>94</sup> A cut-off mean score of 4 has been regarded as indicative of clinically significant fatigue.<sup>94</sup> However, others have suggested a cut-off of 5.<sup>95</sup>

Anxiety and depression was assessed with the questionnaire *Hospital anxiety and Depression (HAD) Scale*.<sup>83</sup> It consists of 14 items divided in a 7 item anxiety and a 7 item depression subscale. The items are rated from 0 (absent) to 3 (extreme present) with a sum score of 42 (21 on each subscale). It has been validated for individuals with chronic SCI.<sup>96</sup> Cut-off of greater than 8 for each subscale indicates the likely presence of clinically significant levels of anxiety or depression.<sup>83</sup>

#### 3.4.1.8 Physical function

Overall, physical function was assessed with the *Spinal Cord Independent Measure, version III* (SCIM).<sup>84</sup> It is a reliable and valid instrument specifically developed for the SCI population.<sup>97</sup> It consists of three subscales concerning self-care, respiration and sphincter management and mobility. Only the mobility subscale was used for these studies. This subscale consists of nine items regarding indoor and outdoor mobility, the ability to climb stairs, the ability to move to and from a car and the ability to get up from the floor and into a wheelchair. The items are weighted according to presumed importance, with the sum score ranging between 0 and 40 points.

In addition, a single question on the ability to get up from the floor was asked: 'If you fall, are you able to get up by yourself without the use of additional aids or help?', which could be answered 'yes' or 'no'.

Walking ability was assessed with the *Walking Index for Spinal Cord Injury* (WISCI) II,<sup>86</sup> which classifies a person's ability to walk 10 metres on a scale from 0 (no ability to stand or walk) to 20 (walks without braces or walking devices). The *Hoffer Ambulation Index*,<sup>85</sup> a four-level Likert scale developed for classifying walking ability in children with cerebral palsy where 1 = community ambulators, 2 = household ambulators, 3 = non-functional ambulators and 4 = non-ambulators. For this study a slight modification was made. Level 1 was divided in 1a = community ambulators without need of walking aids and 1b = community walkers in need of walking aids.

Muscle strength in the lower limbs was assessed with the *Lower Extremity Motor Score* (LEMS) from The International Standard Neurological Classification of Spinal Cord Injury<sup>18</sup> as well as the *Timed Stands Test* (TST).<sup>81</sup> LEMS assesses five key muscle groups (hip flexors, knee extensors, ankle dorsiflexors, long toe extensors, ankle plantar flexors), which are scored from 0 (total paralysis) to 5 (normal; active movement, full range of motion against full resistance in a functional muscle position expected from an otherwise unimpaired person) with the person in a supine position. The total score for each limb ranges from 0 to 25. The TST records the time required to move from a sitting to a standing position ten times without using the hands. The validity of the TST has been tested in many populations with impairments due to neurological conditions, but it has not yet been tested in the SCI population.

#### *3.4.1.9 Walking and wheelchair skills*

Walking skills were assessed with valid and reliable tests for the SCI population: the *10 Metre Walk Test* (10MWT)<sup>87</sup> and the *Timed Up and Go Test* (TUG).<sup>88,98</sup> In 10 MWT, participants are timed walking 10 metres at normal and maximal speed, with necessary assistive devices allowed. The times of two trials for each speed are recorded, and the mean is used for calculations. TUG assesses a person's mobility and requires both static and dynamic balance. It correlates well with other walking tests and has been proven valid for the SCI population. It records the time a person requires to get up from a chair, walk 3 metres, turn around, walk back and sit down again. The test is performed twice, and the mean is used for calculations. Necessary assistive devices are permitted.

Wheelchair skills were assessed by timing a 200-metre wheelchair push (as fast as possible, back and forth on a 50-metre track) and by the ability to ascend a 10-cm curb independently (yes or no).

#### 3.4.1.10 *Physical activity*

Physical activity was defined as any activity that increases energy consumption beyond the resting metabolic rate.<sup>99</sup> The participants quantified their level of physical activity the previous year in one of four categories according to the Public Health Agency of Sweden.<sup>89</sup> 1. Regular exercise and fitness training = exercise and fitness training  $\geq 30$  minutes three or more times/week, 2. Moderate regular exercise = exercise  $\geq 30$  minutes once or twice/week; 3. Light exercise = exercise  $\geq$  two hours/week, and 4. Sedentary = exercise  $< 2$  hours/week. For multiple regression models in studies I and II the categories were dichotomized as regular and not regular exercise.

### 3.4.2 Qualitative interviews

In Study III, fifteen ambulatory subjects were interviewed in depth based on a semi-structured interview guide. The themes in the guide covered the aim of the study: experience of falling and risk of falling, how does falling affect you, circumstances, contributing factors and consequences of falling, fear of falling, knowledge about risk factors and training and attitudes on falls and fall prevention. The sample was strategically selected to obtain wide variability in gender, age, number of years post-injury, level and extent of injury, rural/urban residence and individual experiences of falling and risk of falling. The interviews were conducted at SunRH, in the informant's home or another place selected by the informant. They were taped, transcribed verbatim and analysed using an inductive qualitative content analysis research approach. The interviews were performed by the first author, the transcription by the first author and a student and the analysis by the two authors (VJ and KSR).

## 3.5 DATA ANALYSIS

An overview of the statistical methods used in studies I, II and IV is given in Table 3. The statistical analyses were performed using IBM-SPSS Statistics, version 22.0 (SPSS Inc., Chicago, IL, USA), WINSTEPS<sup>®</sup> version 3.81.0 (Beaverton, OR, USA) and MedCalc Statistical Software version 16.4.3 (MEDCalc Software bvba, Ostend, Belgium; <https://www.medcalc.org>; 2016).

Descriptive statistics are presented as numbers (n), percentages (%) and mean with standard deviation (SD) for normally distributed data, and as median, range (minimum-maximum/min-max) and interquartile range (IQR) for non-normally distributed and ordinal data.

Table 3. Statistical methods used in the studies I, II and IV

Metods	Study I	Study II	Study IV
<i>Descriptive statistics</i>			
Frequency (n), per cent (%)	•	•	•
Median, min-max,	•	•	•
Interquartile range	•	•	•
Mean, SD	•	•	•
<i>Statistical methods</i>			
Independent-samples t-test	•	•	
Mann–Whitney U-test	•	•	
Chi-squared test	•	•	
Spearman's rank correlation		•	•
Fisher's exact test	•	•	
Paired-samples t-test		*	
Multiple logistic regression	•	•	
Chronbach's alpha			•
Bland–Altman method			*
Receiver operating characteristics (ROC)			•
Rasch analysis			•
Survival analysis (Kaplan–Meier plot)		*	

\*Only in this thesis

### 3.5.1 Studies I and II

Odds ratios (OR), with 95 per cent confidence intervals (CIs), were calculated for the factors associated with recurrent falls (>2) and injurious falls. The multiple logistic regression models were analysed using the backwards enter mode, with final predictor variables considered when  $p \leq 0.05$ .

In the retrospective part of the SCIP FALLS study (Study I) the ambulatory individuals had three times higher risks of recurrent falls compared to the wheelchair users, and different factors were associated with falls in these two groups. Therefore, the ambulatory and wheelchair groups were considered as distinctive subgroups and analysed separately in the prospective part (Study II). Data on wheelchair users will be presented elsewhere (thesis; Emelie Butler Forslund, KI, Stockholm, Sweden, February 2017).

#### 3.5.1.1 Additional analyses

Time to first fall calculated with survival analysis and illustrated with a Kaplan–Meier plot. Perceived causes for falls were determined from the structured telephone interview conducted after a fall was reported. The causes listed in the interview were based on the research literature and clinical experience. Up to three different causes could be given for one fall, but one main



cause had to be indicated. Concern about falls was registered at baseline as well as at the exit from the prospective study. The results were compared using a paired t-test. Descriptive statistics and paired samples t-test were used to examine the relationship between retrospective and prospective reported falls.

### 3.5.2 Study III

The analysis in Study III was inspired by Baxter's<sup>100</sup> description of thematic interpretive content analysis, where themes are threads of meaning emerging from the data. The analysis included the following steps:

1. To get an impression of what was being reported all interviews were read several times by the first author. Two interviews were also thoroughly read by the second author.
2. Meaning units were identified, condensed and labelled with codes by the first author guided by the aim of the study. The authors coded four interviews individually and compared the results before deciding on the final coding frame.
3. Data were displayed visually to identify connections within the data and to assist in data reduction. Codes were integrated into a smaller number of subthemes (Table 4) and mutually exclusive and exhaustive main themes.

Table 4. Two examples of the analytic process; at first, the meaning units were condensed and coded, and thereafter the codes were sorted into subthemes.

Meaning unit	Condensed meaning unit	Code	Subtheme
<i>Clearly I'm concerned about falling ... Very, because if you're really unlucky and break a leg or break an arm or something like that, then obviously you are swept back half a year straight away. (man, 78)</i>	Very concerned about breaking an arm or a leg when falling, physical function will be set back half a year	Afraid of consequences	Fall-related psychological issues
<i>I could of course in my own house or something like that, but that's because I try to be, live normally ... Not that I seek out risk situations, I don't feel I'm doing that ... Yeah, trying to live normally at least. (man, 23)</i>	Could have sat down in a wheelchair or isolated myself at home, but will try to live normally within safe limits	Live a normal life/self-identity as a normal and healthy person	Calculated risk taking

4. An abstraction was done in order to identify the overarching content of the text representing the thread of meaning recurring throughout the themes.
5. The findings and interpretations, as well as the authors' own pre-understanding, were discussed repeatedly until a consensus was achieved.
6. Trustworthiness was assessed in terms of credibility, transferability, dependability and confirmability.<sup>101</sup>

### **3.5.3 Study IV**

The BBS showed a ceiling effect and was unable to predict falls in Study II. The Mini-BESTest appeared to be an alternative.<sup>50,59,74</sup> In order to make a comparison of the two balance scales, 46 individuals able to walk 10 metres completed both the BBS and Mini-BESTest.

The floor and ceiling effects of the BBS and Mini-BESTest were calculated and confirmed if more than 15 per cent of the individuals scored either the lowest or highest possible total score.<sup>66</sup>

The internal consistency of the BBS and Mini-BESTest was measured using Cronbach's alpha, where an alpha value between 0.70 and 0.80 was regarded as satisfactory. To investigate the construct validity, a Mann–Whitney U-test was used to compare the subgroups for differences, and Spearman's rank correlation coefficient ( $r_s$ ) was used to check for correlations between continuous variables that were not normally distributed. Correlation coefficients were interpreted as follows: low 0.26–0.49, moderate 0.50–0.69, high  $\geq 0.70$ .<sup>61</sup>

Receiver operating characteristics (ROC) were used to determine the relative ability of the BBS and Mini-BESTest to discriminate known groups: high versus low functional score dichotomised at median, community walkers not using aids versus all other participants, low frequency versus recurrent falls (0–2/>2) and low versus high concerns about falling dichotomised at median.

Further, Rasch analysis was used to evaluate the internal validity of the rating scales of the BBS and the Mini-BESTest. The category structure of the balance scales were examined with values for observed average, the order of categories, outfit mean square (MnSq) values below 2.0, and by observing the probability curves.

#### *3.5.3.1 Additional analysis*

Bland–Altman method was used to investigate the limits of agreement between BBS and Mini-BESTest.

## 4 RESULTS

### 4.1 PARTICIPANTS

Characteristics of the patients in the different studies are shown in Table 5.

Of the 224 individuals included in Study I, 151 were defined as wheelchair users and 73 as ambulatory. The cut-off was determined, with inspiration from Boswell-Ruys et al.,<sup>69</sup> according to the participants' own ratings of the time ratio between wheelchair use and walking to meet mobility needs (wheelchair/ambulating: 0/100, 75/25, 50/50, 25/75 or 100/0). Five participants who stated an equal ratio were discussed and finally classified as ambulatory by the SCIP FALLS Study research group. The ambulatory ratio in Norway was 42 per cent and in Sweden 25 per cent. The total sample consisted of individuals with great variations in terms of their extent of injury, from individuals with little remaining sensorimotor function who were reliant on powered wheelchairs to individuals with almost normal function and no need of aids.

Of the 73 included ambulatory participants, 68 completed the 12-month follow-up for falls, a dropout rate of seven per cent. The reasons for dropouts were three deaths, one withdrawal and one case of insufficient fall data.

Study III was carried out on a Norwegians sample. Eleven participants from Study II were invited to participate, considering that their places of residence were within a reasonable distance to allow face-to-face interviews, and ensuring a variety in age, injury and functional levels and socio-demographic variables. One elderly individual (> 80 years of age) declined to participate due to poor health. To ensure information power<sup>102</sup> and to add to the variety of experiences in regard to falls, five additional individuals were recruited after the recruitment for Study II was completed. Altogether, the sample in Study III was comprised of 15 informants.

All 47 participants from the Norwegian cohort of the SCIP FALLS Study in Study I, who were able to walk 10 metres independently with or without walking aids, were included in the sample for Study IV. One participant failed to perform the Mini-BESTest and was thus excluded.

Table 5. Characteristics of the participants in all the studies. Values are presented as n (%), or as otherwise stated.

Characteristics	Study I (n=224)	Study II (n=68)	Study III (n=15)	Study IV (n=46)
Male	173 (77)	45 (66)	(67)	32 (70)
Age, mean years (SD)	50 (15)	55 (15)	47(18)	55 (17)
Educational level				
Secondary school or less	73 (33)	23 (34)	5 (33)	21 (46)
High school	66 (30)	20 (29)	4 (27)	11 (24)
College/university	83 (37)	25 (37)	6 (40)	14 (30)
Work				
Not working	123 (55)	41 (60)	10 (67)	37 (80)
Working	101 (45)	27 (40)	5 (33)	9 (20)
<b>SCI characteristics</b>				
Duration of injury				
Median years (min–max)	15 (1–56)	12 (1–40)	7 (2–34)	7 (1–41)
Injury level				
Cervical	114 (51)	42 (62)	7(47)	30 (65)
Thoracic (T1–6)	33 (15)	1 (2)	0 (0)	1 (2)
Thoracic (T7–12)	59 (26)	17 (25)	3(20)	7 (15)
Lumbar	18 (8)	8 (12)	4 (27)	8 (17)
Completeness of injury <sup>1</sup>				
AIS A	100 (45)	2 (3)	0 (0)	1(2)
AIS B	31 (14)	1 (2)	0 (0)	1 (2)
AIS C	20 (9)	3 (4)	2 (13)	3 (7)
AIS D	73 (32)	62 (91)	13(87)	41 (89)
LEMS <sup>2</sup> , median (min–max)	0 (0–50)	45 (19–50)	–	46 (20–50)
Injury mechanism				
Sport	51 (23)	14 (21)	3 (20)	9 (20)
Violence	3 (1)	0 (0)	0 (0)	1 (2)
Traffic	91(41)	22(33)	8 (53)	13 (28)
Fall	69 (32)	28 (39)	3(20)	21(46)
Other	10 (4)	4 (6)	1(7)	2 (4)
<b>Functional characteristics</b>				
SCIM motor <sup>3</sup> , median (min–max)	19 (3–40)	39 (19–40)	–	37 (8–40)
WISCI <sup>4</sup> , median (min–max)	–	20 (12–20)	–	20 (9–20)

<sup>1</sup> AIS =American Spinal Injury Association impairment scale. A= complete injury, B= sensory incomplete injury, C= Motor incomplete injury; more than half of the key muscles have muscle grade <3, D= motor incomplete injury; at least half of the key muscles have muscle grade ≥3.

<sup>2</sup>LEMS=Lower extremity motor score according to International Standard Neurological Classification of Spinal Cord Injury, sum score 0–50 points.

<sup>3</sup>SCIM = Spinal Cord Independence Measure III, motor items sum score 0–40 points.

<sup>4</sup>Walking Index for Spinal Cord Injury II, sum score 0–20 points.

## 4.2 FALLS AND ASSOCIATED FACTORS IN INDIVIDUALS WITH SCI

Seventy-six per cent of the total sample (n=224) reported falling and 51 per cent reported recurrent (>2) falls in the previous year. The final multiple regression model showed that ambulatory individuals were 2.9 times more likely to report recurrent falls compared to wheelchair users. Further, those who were able to get up from the ground by themselves were 2.2 times more likely to report recurrent falls than those who were not able to do so. In addition, those who exercised regularly for at least 30 minutes once or twice a week were 1.9 times more likely to report recurrent falls compared to those who exercised less. With increasing age, the odds of reporting recurrent falls decreased 3 per cent per year (Table 6).

As mode of mobility was the factor associated with the highest OR for recurrent falls and the distinction is clinically important, separate subgroup models were run for wheelchair users and ambulatory individuals. For ambulatory individuals, the odds of reporting recurrent falls were 4.7 times greater than for those who were able to get up by themselves from the ground. Further, the odds decreased 24 per cent per increasing scale-step on the International SCI Quality of Life Scale (i.e. with increasing quality of life).

**Table 6.** The final multiple logistic regression models for the total sample and for the ambulatory subgroup showing factors associated with recurrent (>2) falls. First category is a reference for the categorical variables unless otherwise is stated. No decimals indicated if  $OR \geq 10$

Variable	$\beta$	OR	95% CI	p-value
<b>Total sample</b>				
Age	0.12	0.97	0.95–0.99	0.012
Gender (ref. woman)	0.48	1.61	0.80–3.24	0.182
Wheelchair or ambulatory	1.08	2.93	1.43–6.03	0.006
Able to get up by one–self (no/yes)	0.77	2.15	1.16–3.99	0.015
Exercise previous year (no/yes)*	0.64	1.90	1.09–3.38	0.029
<b>Ambulatory subgroup</b>				
Age	–0.00	1.00	0.96–1.03	0.850
Gender (ref. woman)	–0.10	1.10	0.34–3.60	0.869
Able to get up by one–self (no/yes)	1.57	4.74	1.06–21	0.042
General quality of life**	–0.28	0.76	0.59–0.99	0.045

Overall model fits (Hosmer and Lemeshow test):

**Total sample:**  $\chi^2=6.135$ ,  $df=8$ ,  $n=223$ ,  $p=0.632$

**Ambulatory subgroup:**  $\chi^2=6.953$ ,  $df=8$ ,  $n=73$ ,  $p=0.542$

\* No ‘regular’ or ‘regular’ exercise previous year. \*\* International SCI Quality of Life Basic Dataset.

### **4.3 FALLS, INJURIOUS FALLS AND THEIR PREDICTORS IN AMBULATORY INDIVIDUALS WITH SCI**

During the one-year registration period, 272 falls were reported, with sports-related falls excluded. Twelve participants (18%) did not fall, 17 (25%) fell once, six (9%) fell twice and 33 (48%) fell three times or more. The median number of falls was 2 (Q1–Q3: 1–6), with the highest number being 23. The peak prevalence for falls was in the middle age range group (46–60 years).

At least one injurious fall was reported by 44 of the participants (65%), median number being 1 (Q1–Q3: 0–2). Women reported significantly more falls than men. Injurious falls were positively correlated with the number of reported falls ( $r_s=0.74$ ,  $p\leq0.001$ ). Of the reported falls 41% were injurious. Of the injurious falls 84% resulted in minor injuries, 16 per cent in moderate or serious injuries. Nine participants (13%) sustained a moderate injury. Three participants (4%), all women above the age of 55, sustained serious injuries.

Forty-six per cent of the falls occurred indoors. Most falls (60%) happened in the daytime, were spread throughout the week and occurred during a variety of activities. The activity that accounted for most indoor falls was getting in and out of a chair (20%). Walking on uneven or slippery surfaces accounted for most outdoor falls (31% and 21%, respectively). Although not reaching significance ( $p=0.054$ ), more moderate and serious injuries tended to occur indoors (13 vs. 6) while more falls with minor injuries occurred outdoors (135 vs. 113).

Two data punching errors regarding the independent variable fear of falling were detected after Study II was submitted to the journal. However, when correcting for these errors, the final multiple logistic models for recurrent and injurious falls were not altered, but the numbers are somewhat changed. The corrected final multiple regression models for recurrent falls and injurious falls are presented below and in Table 7.

The final multiple logistic regression model (Table 7) showed that the odds of recurrent falls were at least 8.6 times higher (lower CI) for individuals with a history of recurrent falls in the previous year compared to those without such a history, and 6.1 times higher for individuals who were afraid of falling compared to those who had no such fear. With increasing time spent walking 10 metres, the odds of recurrent falls increased by 31 per cent per second. The wide CI and difficulties with estimating the true OR for recurrent falls in the previous year (as displayed in Table 7) were caused by the small sample size. The final model explained 47–62 per cent of the variation in the dependent variable recurrent falls, and 87 per cent of all cases were correctly

Table 7. The final multiple logistic regression models showing predictors for recurrent (>2) falls and injurious falls in ambulatory individuals. First category is reference for categorical variables. No decimals indicated if OR $\geq$ 10.

Variable	$\beta$	OR	95% CI	p-value
<b>Recurrents falls</b>				
Ten Metre Walk Test, max. speed (s)	0.27	1.31	1.02–1.68	0.034
Falls previous year (0–2/>2)	4.71	111	8.58–1425	$\leq$ 0.001
Fear of falling (no/yes)	1.81	6.09	1.43–26	0.015
<b>Injurious falls</b>				
Age (years)	0.04	1.04	0.99–1.08	0.093
Gender (man/woman)	1.00	2.71	0.68–11	0.158
Falls previous year (0–2/>2)	1.43	4.16	1.21–14	0.023
Fear of falling (no/yes)	1.45	4.25	1.26–14	0.018

Overall model fit (Hosmer and Lemeshow test):

**Recurrent falls;** Chi<sup>2</sup>=11.28, df=8, n=67, p=0.127. Cox & Snell R<sup>2</sup>= 0.47, Nagelkerke R<sup>2</sup>=0.62

**Injurious falls;** Chi<sup>2</sup>=6.58, df=8, n=68, p=0.133. Cox & Snell R<sup>2</sup>= 0.25, Nagelkerke R<sup>2</sup>=0.34

classified as recurrent fallers. The odds of injurious falls were 4.2 times higher for individuals with history of recurrent falls previous year compared to those without, and 4.3 times for individuals afraid of falling compared to those not afraid of falling (Table 7). The final model explained 25–34 percent of the variation in the dependent variable; 77 percent of all cases were correctly classified as having an injurious fall.

### 4.3.1 Additional results

#### 4.3.1.1 Time to first fall

When investigating falls in all 73 included participants, 57 (84%) fell at least once. By six months, 25 of the 71 (35%) participants that were still being followed had fallen three times. The mean time to first fall was 19.7 (95% CI 15.3–24.2) weeks, and to the third fall it was 37.5 (95% CI 33.2–41.8) weeks (Figure 7).

#### 4.3.1.2 Perceived reasons for falls

The participants perceived loss of balance, muscle weakness and hazards in the indoor and outdoor environments as main causes in 64 per cent of the fall incidents: hazards in 26 per cent of the outdoor and 10 per cent of the indoor falls and muscle weakness in 26 per cent of the indoor falls and 11 per cent of the outdoor falls. However, in 45 per cent of the falls, a combination of causes was reported. There was no significant correlation between balance control measured with

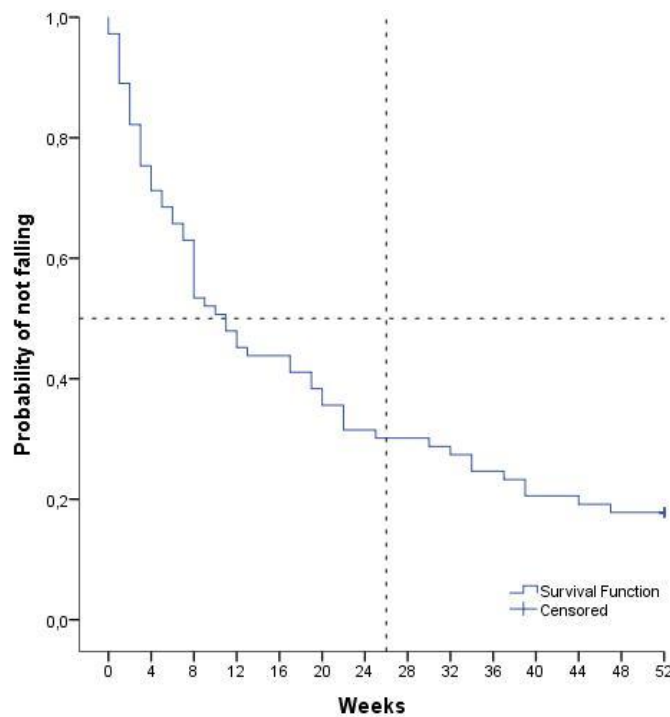


Figure 7. Kaplan–Meier plot showing time to first fall for all ambulatory individuals included in Study II. The dotted vertical line indicates 6 months (26 weeks) and the dotted horizontal line the 50 per cent probability of not falling (n=73).

BBS and recurrent falls ( $p=0.076$ ), although there was a negative but low correlation between the number of falls and BBS ( $r_s=-0.27$ ,  $p=0.024$ ).

#### 4.3.1.3 Fall-related psychological aspects

At baseline, the mean score on concern about falling (FES-I) for the ambulatory group (n=73) was 29.4 (SD 8.2). There were no significant differences between participants younger than 65 years of age and those 65 years or older in the FES-I scores ( $p=0.591$ ). Forty-six participants (63%) reported that they were afraid of falling, 19 (26%) were somewhat concerned, 18 (25%) were fairly concerned and 9 (12%) were very concerned. There were no significant differences between participants younger than 65 years of age and those 65 years or older in regard to reported fear of falling ( $p=0.512$ ).

At the 12-month follow-up, 58 of the 73 included participants (79%) answered the FES-I questionnaire and 64 (88%) answered the question on fear of falling (yes/no). The mean score on the FES-I was 30.6 (SD 9.2). The mean paired difference was 1.5 points (95% CI -2.9 to -0.1), and the standard error of the mean (0.715) demonstrated a significant ( $p=0.040$ ) difference. There was



significantly less reported fear of falling at follow-up compared to at baseline (49% vs. 56%,  $p=0.010$ ).

#### 4.3.1.4 Falls from a retrospective and a prospective perspective

There were significantly fewer falls registered falls ( $p<0.001$ ) and significantly fewer recurrent fallers ( $p<0.001$ ) identified at the 12-month follow-up compared to the retrospectively reported falls and recurrent falls previous year at baseline (Figure 8). Table 8 displays the relationship between retrospectively reported and prospectively registered falls.

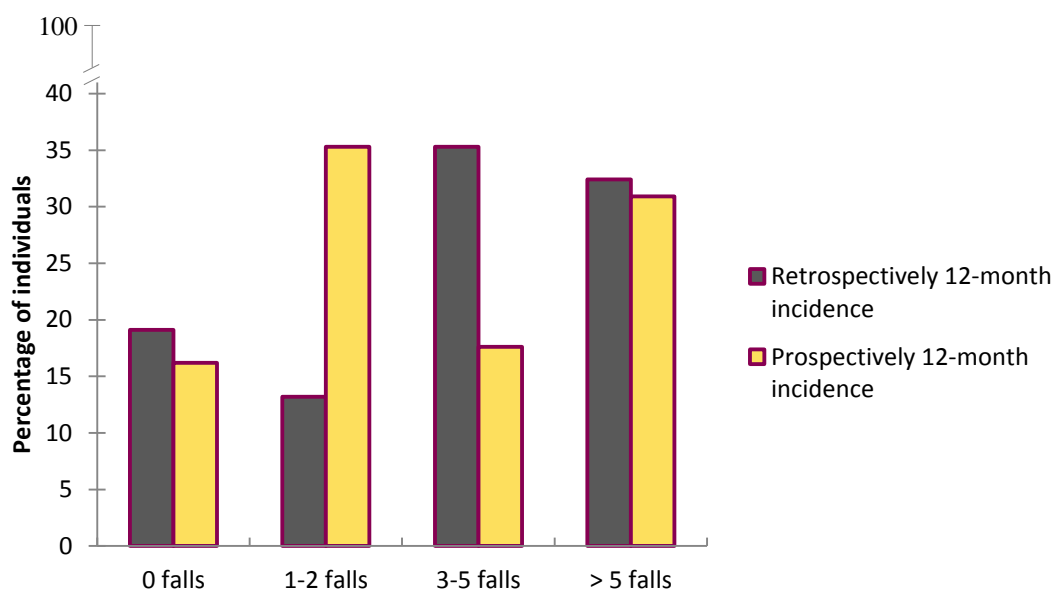


Figure 8. The 12-month fall incidence reported retrospectively and prospectively by the ambulatory individuals in Study II (n=68).

Table 8. Prospectively registered falls from baseline plotted against falls the previous year reported at baseline for the ambulatory individuals in Study II (n=68).

		Falls previous year			
		0	1-2	3-5	>5
Prospectively registered falls	0	3	3	2	4
	1-2	10	5	5	3
	3-5	0	1	10	2
	>5	0	0	7	13

## 4.4 INDIVIDUAL PERSPECTIVES ON FALLS AND FALL RISK

The analysis of the interviews with 15 ambulatory individuals revealed one overarching theme, 'Falls challenge identity and self-image as normal'. This was comprised of two main themes interpreting the informants' experience of how falls, risk of falling and fall-related consequences were influenced by their incomplete SCI; 'Walking with incomplete SCI involves minimising fall risk and fall-related concerns without compromising identity as normal' and 'Walking with incomplete SCI implies a willingness to increase fall risk in order to maintain identity as normal'. The two main themes were formed by seven subthemes which represented the informants' contradictory view of falls; on one hand, the enhanced risk of falling and falls was considered to be a part of life, and the informants developed preventive strategies and justified their concerns to protect their vulnerable bodies against falls and fall-related consequences. On the other hand, they described a willingness to take risks to emphasise a normal identity (Figure 9).

Maintaining an identity and self-image as normal was important for the informants, and falling in everyday situations was perceived as embarrassing and threatened their self-image.

*... it's embarrassing... They all stand there watching, and you look like an idiot, and a whole lot of them think I'm drunk, you know. (woman, 43)*

*...you feel simply a bit handicapped, and you don't want to admit that. (man, 39)*

To avoid falls, they used several preventive measures, and many talked about their enhanced fall risk awareness and how they coped with challenging fall risk situations.

*...the head becomes a sort of control freak in relation to the body. Yeah, so there's a lot of head traffic, just like to go out for a walk (in the winter). (woman, 32)*

Although trying to avoid falls, most informants regarded falls as a part of life and they tried to protect their vulnerable bodies by using protective strategies when falling to prevent injury.

*... I try... to actually not put my hands in front of me, I try to protect my body, use my hands to protect my head, protect my belly, protect myself instead... (man, 29)*

However, for a few informants, mostly women who had been injured in falls, falling was a big concern and restricted their activities. One 26-year-old woman having difficulties getting up from the ground independently stated, *... I don't go to places where there are no people*. Losing control

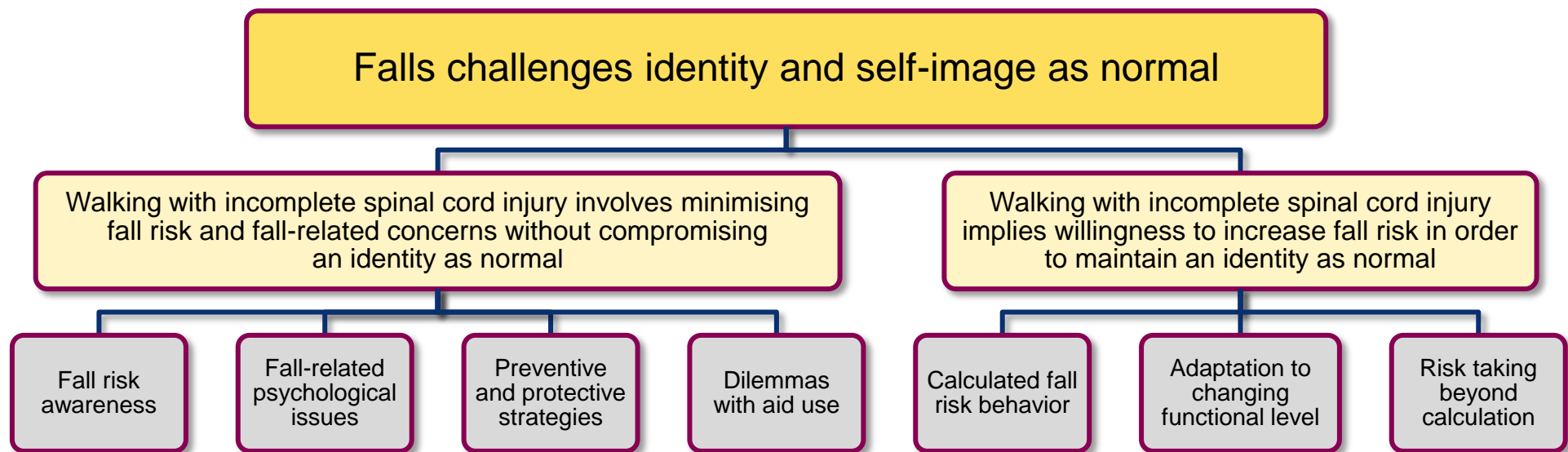


Figure 9. Overview of results showing that perceptions of falls and fall risk in ambulatory individuals with incomplete SCI could be expressed in one overarching theme, two main themes, and seven subthemes.

of the body could also be the cause of fear, especially when this was related to the fall causing the spinal cord injury:

*so it's turned into a fear of losing control, because it was the fact that I lost control of the moped that made me fall over the steering wheel..... That's the kind of things I'm left with, that deep fear. (woman, 32)*

The majority of the informants took calculated risks but within safe limits, balancing benefits versus risks, in order to live their lives on their own terms. However, they were also willing to pay the price of falling in order to maintain a healthy self-image. Moving around without fall risk was looked upon as impossible because the alternative was some degree of inactivity and dependence.

*I could of course have sat down in a wheelchair or, isolated myself in my own house or something like that, but that's because I try to be, live normally... Not that I seek out risk situations, I don't feel I'm doing that... (man, 23)*

Informants experiencing a deterioration of function after long lives with SCI, who were opposed to accepting the consequences of their poorer functioning, thus experienced and accepted an even higher fall risk. There were informants who were willing to take risks beyond the normal calculated ones. They exceeded both their own, peers' and family members' levels of comfort in order to achieve higher functional levels.

*... I kind of have to challenge myself a little and... You don't become a good skier without wiping out a few times. A lot of people would probably say that I'm a risk-taker... (man, 57)*

## **4.5 ASSESSMENTS OF BALANCE CONTROL**

BBS showed a ceiling effect as 28 per cent of the participants achieved the maximal sum score, whereas no floor or ceiling effect was observed for the Mini-BESTest (Figure 10). Both scales showed excellent internal consistency, with a Chronbach's alpha of  $\geq 0.94$ . The correlation between Mini-BESTest and BBS was high ( $r_s = 0.90$ ,  $p < 0.001$ ) confirming high criterion validity (Figure 10). The sum scores correlated highly with 10 MWT maximal speed, SCIM III mobility items and TUG ( $r_s > 0.70$ ), showing high construct validity for both scales.

BBS and Min-BESTest were able to discriminate (known groups validity) community walkers not using walking aids ( $p < 0.001$ ) from individuals using mobility aids, with cut-off points at  $>47/56$

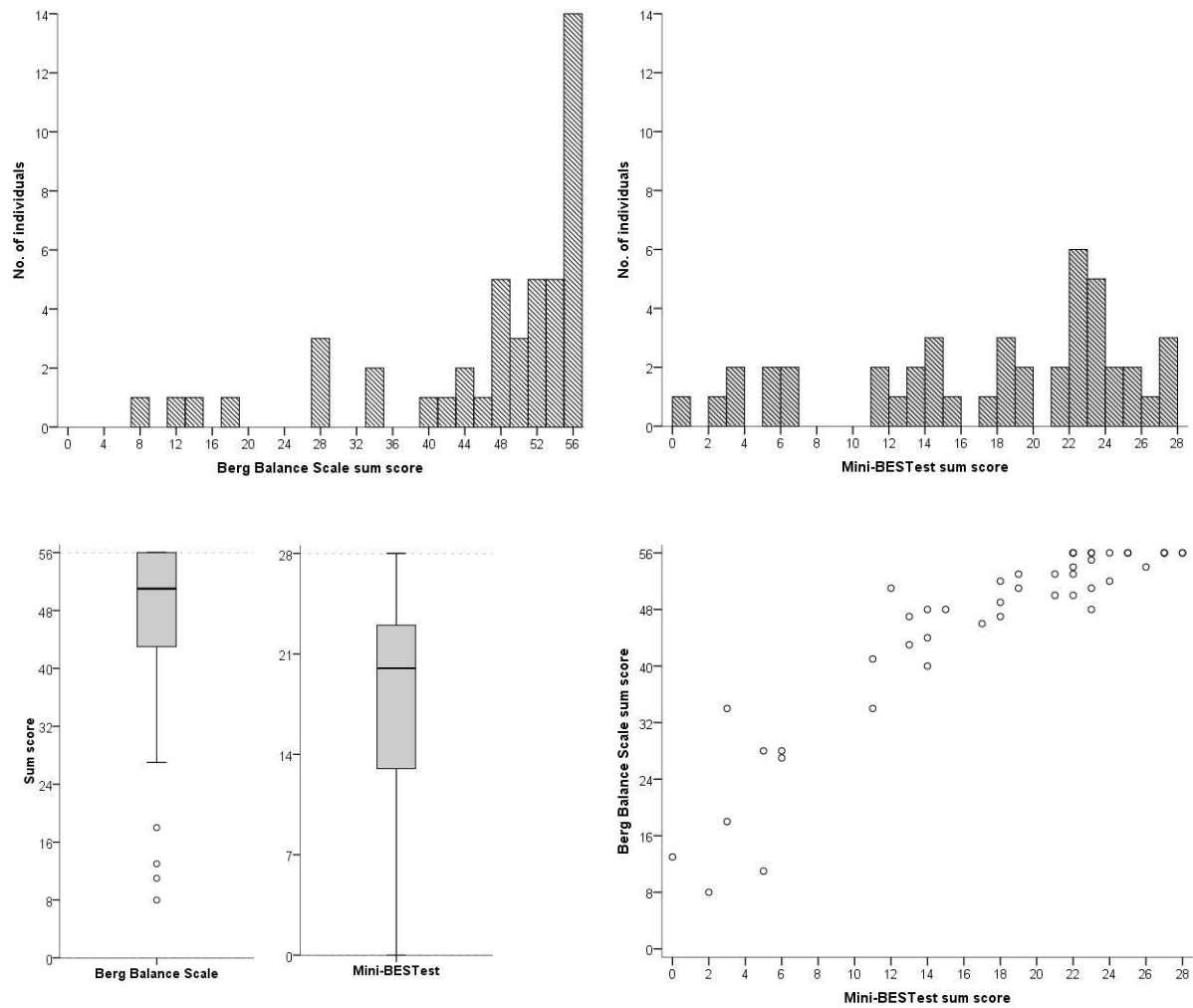


Figure 10. Distribution of sum scores (A, B), Box and Whiskers plot with median and range of sum scores (C) and correlation (D) between sum scores on the Berg Balance Scale (sum score 0–56 points) and the Mini-BESTest (sum score 0–28 points) (n=46). Each dot in Figure D represents one or more individuals.

on the BBS and  $>19/28$  on the Mini-BESTest for community walkers without aids. The scales could also discriminate between participants with low ( $p < 0.001$ ) and high concerns about falling, with cut-off points of  $\leq 46/56$  on the BBS and  $\leq 19/28$  on the Mini-BESTest for high concern. However, the specificity of the BBS in discriminating low and high concerns about falling was low (55%). None of the scales could discriminate between participants with infrequent and recurrent falls ( $p = 0.78$  for the BBS and  $p = 0.64$  for the Mini-BESTest) (Figure 11).

All possible response answers on the rating scales were used in both balance scales. However, there was a very low frequency (2–5%) for response categories 1 and 2 on the BBS (ranging from 0–4). Good person response validity was found for BBS and Mini-BESTest with two (4%) and

one (2%) participant, respectively, showing person misfit. The BBS was able to distinguish two groups with a separation index of 1.68 and a person reliability value of 0.74. The Mini-BESTest was able to distinguish more than three groups with a separation index of 2.95 and a person reliability value of 0.90. Person-item maps are shown in figures 12 and 13. For the BBS, one item was at the bottom (easiest item) of the logit scale, and no items were in the upper quarter (more difficult items) of the logit scale. The participants were spread over most of the logit scale; 46 per cent ( $n = 21$ ) were in the upper quarter, and 7 per cent ( $n = 3$ ) were in the lower quarter. For the Mini-BESTest items were spread from 25–75 per cent of the logit scale with no items at either the top or at the bottom, and the participants were spread across the entire logit scale.

#### **4.5.1 Additional results**

It is presumed that the BBS and Mini-BESTest both measure the construct of balance control. The correlation between the two scales was high in this study ( $r_s = 0.899$ ,  $p < 0.001$ ). However, this correlation does not tell anything about the agreement between the two scales. To investigate the limits of agreement, the Bland–Altman method was applied.<sup>103</sup> The null hypothesis was that there would be no variation in the mean differences, which was tested with a one-sample t-test. This test showed a highly significant ( $p < 0.001$ ) mean difference, 19.3 per cent (CI; 22.9 to 15.7), with BBS having the highest scores, thus indicating no agreement.

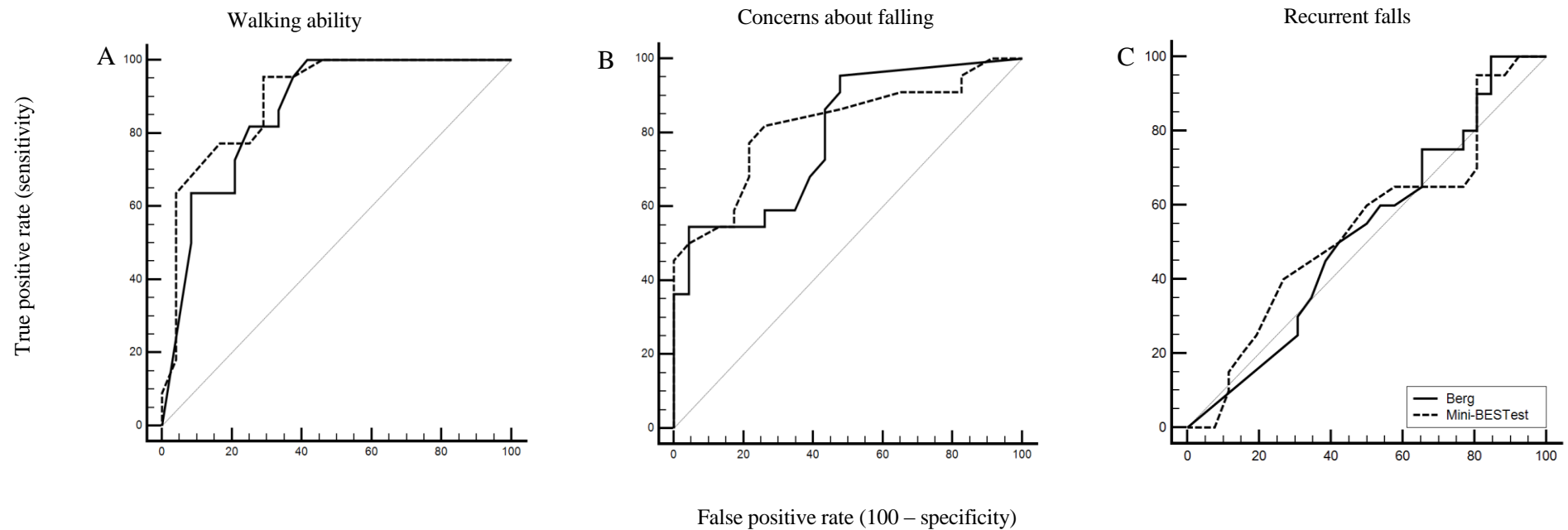


Figure 11. Receiver Operating Characteristic (ROC) curves of the Berg Balance Scale and the Mini-BESTest for classifying individuals according to A. walking ability (community walker not dependent on walking aids versus individuals using mobility aids) (n=46), B. low (FES I  $\leq 27$ ) versus high (FES-I  $>27$ ) concerns about falling (n=46) and C. recurrent ( $>2$ ) falls versus infrequent falls ( $\leq 2$ ) (n=45).

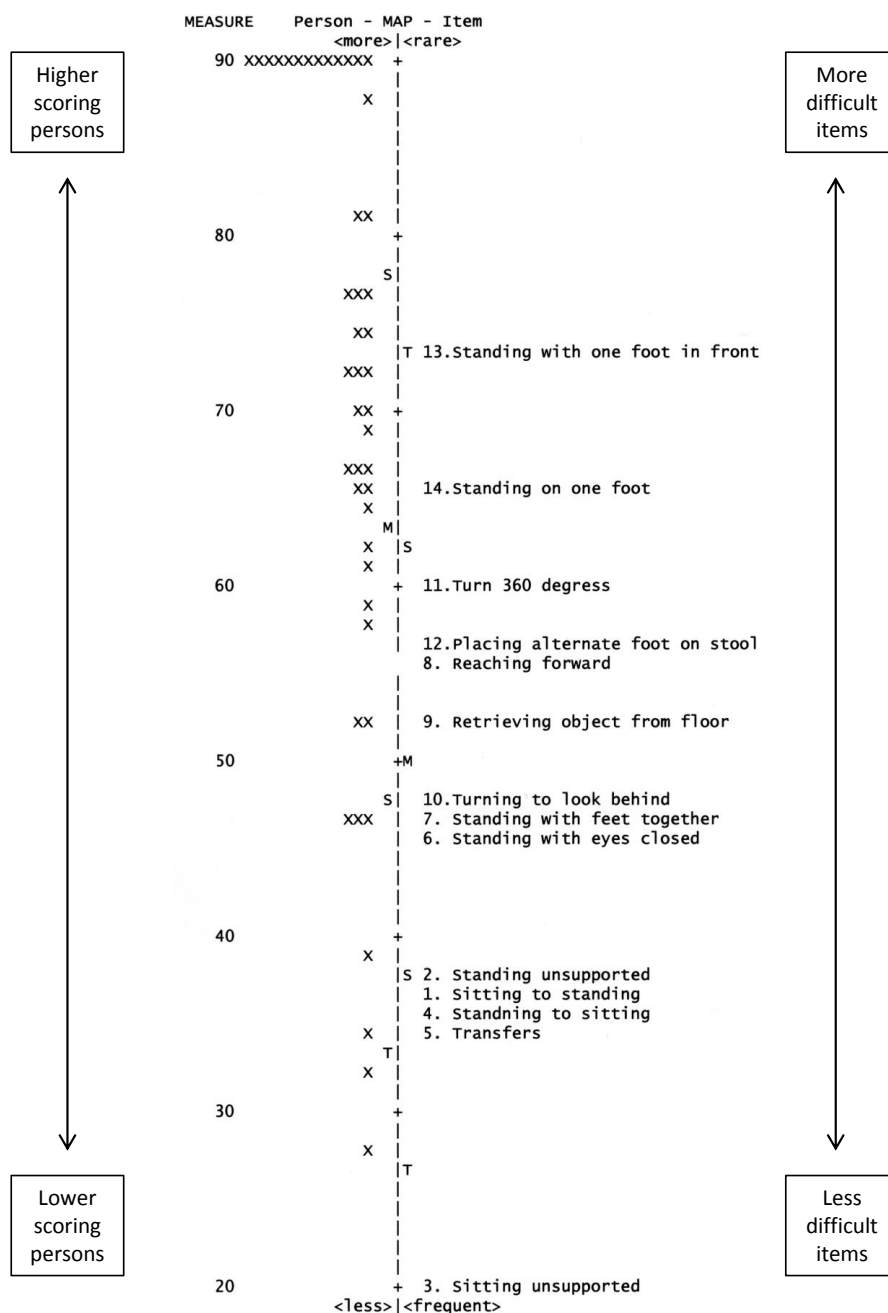


Figure 12. Person-item map for the Bergs Balance Scale. Hierarchies of participant scores and item calibrations are displayed on a common logit scale which has been transformed to a possible range of 0 to 100. Each participant is presented by the symbol “x” on the left side of the scale (dotted vertical line). The distribution of items in order of difficulty is shown to the right of the scale. For both distributions median (M), one standard deviation (S) and two standard deviations (T) are indicated, for persons on the left side and for items on the right side of the scale.



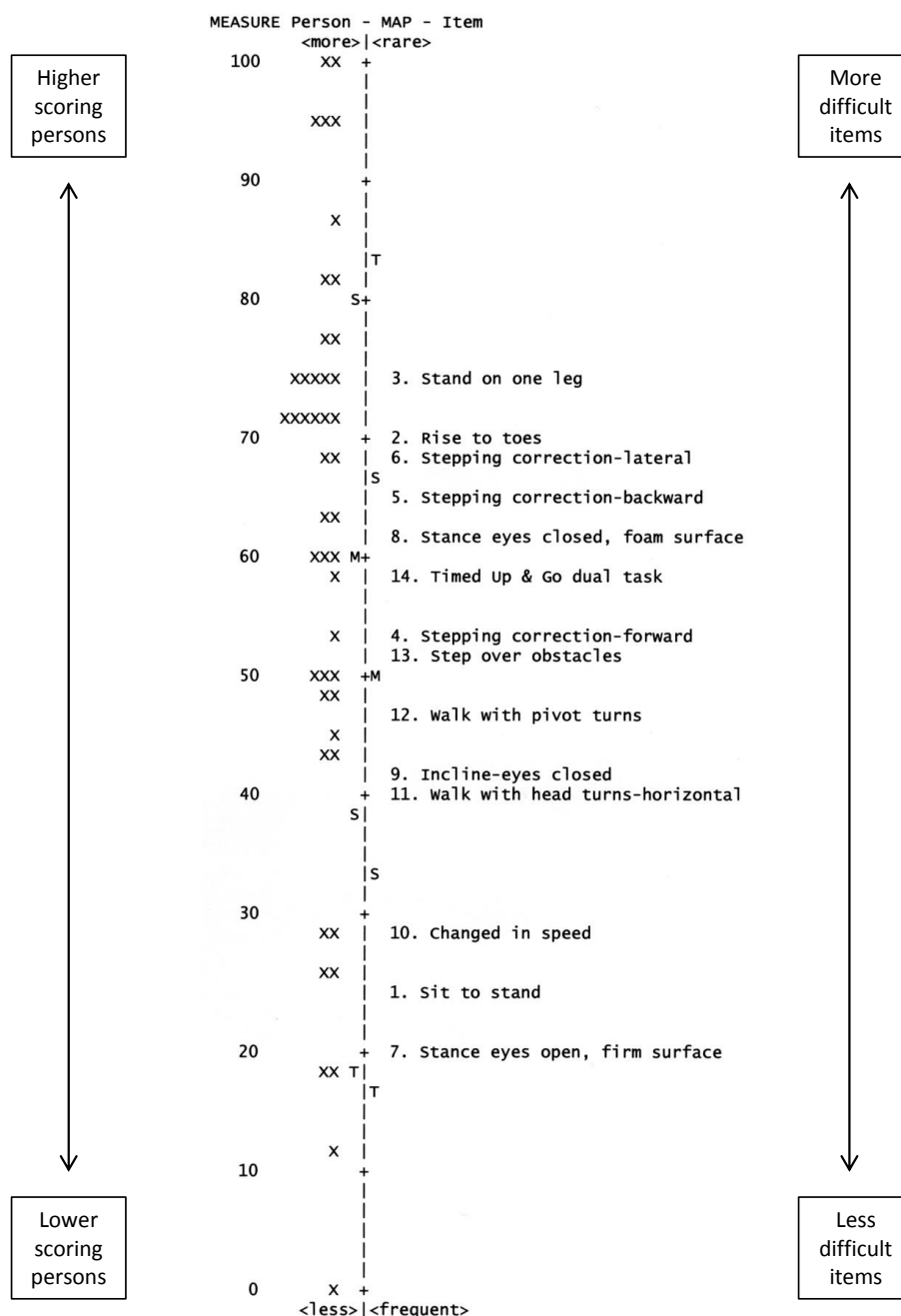


Figure 13. Person-item map for the Mini-BESTest. Hierarchies of participant scores and item calibrations are displayed on a common logit scale which has been transformed to a possible range of 0 to 100. Each participant is presented by the symbol “x” on the left side of the scale (dotted vertical line). The distribution of items in order of difficulty is shown to the right of the scale. For both distributions median (M), one standard deviation (S) and two standard deviations (T) are indicated, for persons on the left side and for items on the right side of the scale.



## 5 DISCUSSION

### 5.1 MAIN FINDINGS

Falls in individuals with SCI were frequent, and half of the total study sample reported recurrent falls in the previous year. Mode of mobility was an important factor associated with recurrent falls, as ambulatory individuals had higher odds than wheelchair users. Ability to get up from the ground, regular exercise and younger age were also associated with recurrent falls. A subgroup analysis indicated that the factors associated with recurrent falls differed for wheelchair users and ambulatory individuals.

Fifty-six (82%) of the ambulatory individuals reported falling during the 12-month follow-up, and 33 (49%) had at least three falls. Forty-four (65%) individuals experienced at least one injurious fall, with most injuries being minor. Three individuals, all menopausal women, had a serious injury. Reporting recurrent falls in the previous year and fear of falling were predictors of both recurrent falls and injurious falls in ambulatory individuals. In addition, slower walking speed was a predictor, although weak, for recurrent falls.

The ambulatory informants interviewed in the qualitative study considered falls to be a part of life. They were aware of their increased fall risk and used various preventive measures to avoid falls. Nevertheless, when important to their self-identity they were also willing to expose themselves to fall-risk situations. However, falls especially in every-day situations interfered with their identities and self-images as normal, healthy, and well-functioning individuals. All the informants expressed some conditional fall-related concerns i.e. walking on slippery surfaces, but a few had inexpedient concerns limiting their activities and participation in society.

Lack of balance was perceived as one of the main causes for falls. Yet, when measuring balance control with the BBS, no association with recurrent falls was found. Thus, a newer and presumably more sensitive balance scale, the Mini-BESTest, was tested. Both the BBS and Mini-BESTest proved to be valid scales for assessing balance control in individuals with chronic SCI who were able to walk. The Mini-BESTest seemed to be the preferable instrument in this sample due to its lack of ceiling effect and better scale properties. However, neither the BBS nor the Mini-BESTest could predict recurrent falls.

## 5.2 FALLS

To the best of our knowledge, no other study has followed a representative cohort of ambulatory individuals with traumatic SCI over one year to establish the annual incidence of falls. We found that falls were very common, as 82 per cent of the participants reported at least one fall, and 49 per cent reported experiencing recurrent falls during the 12-month follow-up. Due to the disparity in the designs, it has been difficult to compare our results with those from other studies. The six-month incidence of at least one fall in Study II was 71 per cent. This is high compared to the prospective study of Phonthee et al. from Thailand (39% in six months),<sup>7</sup> but not unlike the findings of Wirz et al. from Switzerland (61% in five months).<sup>10</sup> Slippery and difficult walking conditions during wintertime pose an extra fall risk to able-bodied as well as disabled people, especially in the Nordic countries, and such conditions were reported as a main cause in 20% of the outdoor falls in the present study. This may be one explanation for the discrepancy with the findings of Phonthee et al. The incidence of falls is also much higher than reported for healthy adults (18%–41%),<sup>104,105</sup> which highlights the elevated fall risk in this population.

The middle age group (46–60 years) had the highest fall incidence, which is similar to findings in other populations.<sup>37</sup> This age group had a somewhat higher percentage of women (40%) compared to the percentage in the total sample of ambulatory individuals. It has been suggested that a loss of oestrogen production may play a role in muscular contraction mechanisms, thus increasing fall risk and leading to higher fall rates in postmenopausal women.<sup>106</sup> The middle age group also had the highest median time post-injury (16 years), and therefore more participants in this age-group could be exposed to functional decline.<sup>107</sup> Clinical experience, supported in studies,<sup>107</sup> shows that individual patterns of activity and participation are not always adjusted for this physical decline, thus increasing the fall risk.

## 5.3 ADVERSE CONSEQUENCES OF FALLS

Falling may only represent a problem if it results in negative consequences, such as injuries, difficulties in getting up, concerns about falling that limit activities and participation in society or other psychological consequences like damage to identity.

### 5.3.1 Fall-related injuries

Injurious falls in ambulatory individuals may add to their disabilities for shorter or longer periods of time. A hand fracture might result in wheelchair use for a person reliant on crutches for walking. This in turn may cause additional deconditioning, which, of course, is undesirable. In this

ambulatory sample, 41 per cent of the reported falls resulted in injuries, and 65 per cent of the participants experienced at least one injurious fall. However, most of the injurious falls only caused minor injuries (minor bruises and abrasions), as defined by Schwenk et al.<sup>36</sup> The proportion of individuals that experienced moderate and serious injuries (17%) was similar to that found in other studies.<sup>3,6,10,15</sup> Ambulatory women with SCI reported more injurious falls than their male peers, a finding also reported in healthy adults.<sup>104</sup> Moreover, all fractures occurred in postmenopausal women, which has also been shown by other authors,<sup>106</sup> and women are known to have a higher lifelong fracture rate compared to men.<sup>108</sup> However, gender was not a significant predictor of injurious falls in the final model although significant in the bivariate analysis. This may be due to the small sample size.

Almost half of the falls in the ambulatory individuals occurred indoors, and there was a trend towards more moderate and serious injuries indoors compared to outdoors. Some individuals with poorer function in this sample walked indoors but not outdoors, thus elevating their indoor fall risk. In addition, limited space and more hard surfaces, edges and corners to hit in an indoor environment may cause more injuries when falling and explain this finding. Moreover, injurious falls were significantly correlated to the number of falls. An implication of this finding is that by reducing fall incidence, injury incidence may fall as well.

### **5.3.2 Fall-related psychological aspects**

A majority of the participants reported being afraid of falling and 27 of the 73 included in Study II said they were fairly or very afraid of falling, which equals findings in the elderly.<sup>109</sup> However, the mean score on the FES-I was 29 points, which is high compared to the elderly,<sup>39,110</sup> but comparable to individuals with PD.<sup>111</sup> Some level of fall-related concern can be considered a protective response to a realistic threat,<sup>112</sup> but the association between falls and fall-related psychological aspects remains unclear.

Both falls and fall-related experiences may cause concerns. Having experienced injurious falls or not being able to get up after a fall, seemed to be mediators of developing fall-related concerns by the informants in Study III as reported in the elderly.<sup>113</sup> Learning and practicing how to fall and how to get up by one-self may be relevant strategies to avoid injurious falls and reduce fear of falling.

SCI caused by falls may subsequently lead to concerns about falling. Several informants in Study III expressed excessive fear and catastrophic thoughts about falling and related this fear to the fall that caused their SCI or to other daunting falling experiences such as not being able to

get up after a fall. In community-dwelling older adults approximately 10 per were shown to have excessive levels of perceived fall risk strongly related to psychological factors.<sup>114</sup> Delbaere et al. suggest that such excessive fear should be taken seriously and managed with cognitive behavioural interventions.<sup>115</sup> They also argue that high levels of perceived fall risk may lead to future falls, independent of physiological risk, and that the disparity between physiological and perceived fall risk contributes to fall risk mainly through psychological pathways. Cognitive behavioural therapy, especially in combination with exercise, has shown the ability to reduce the fear of falling in the elderly.<sup>112,116,117</sup>

Moreover, the recognition of being at risk<sup>40</sup> due to underlying factors such as impaired balance control, muscle weakness or impaired sensation, which are typical for this population, may be a realistic source of concern. This is supported in a study of young and old women where fall-related concerns limiting activity were associated with early reduction of functional mobility rather than psychological factors<sup>118</sup> and in a recent study of individuals with late effects of polio, dynamic balance and gait performance were determinants of fall-related concerns.<sup>119</sup> On the other hand, there are emerging studies showing that fear causes muscular co-activation, resulting in reduced adaptation to balance challenges,<sup>120,121</sup> thereby increasing fall risk and consequently causing falls.

Fear of falling and concerns about falling have been found to be two different constructs measuring related, but unique aspects of fall-related psychological issues.<sup>47</sup> The participants' fear of falling was somewhat reduced at the 12-month follow-up. On the other hand, concerns about falling, as measured with the FES-I, showed a significant increase of one point. However, this finding was considered to be of little clinical importance and probably within the measurement error.<sup>111</sup> The questions at baseline were answered when attending the check-ups in the rehabilitation hospitals, whereas at the 12-month follow-up the participants answered the questions at home and mailed them to the investigators. This difference in circumstances may have influenced the answers. Three persons had serious fall-related injuries during the follow-up period. When looking closer at fall-related concerns, two scored exactly the same on the FES-I at baseline and the 12-month follow up, while for one the scores decreased by 2 points at follow-up. Two expressed a fear of falling at baseline while the other expressed no fear. However, no one expressed fear of falling at follow-up. This indicates that there were no changes in fall-related concerns after a severe injury in this study.

Nevertheless, concerns about damage to identity might be as prominent as worries about the functional consequences. A fall, especially in everyday situations, seemed to remind the

informants in Study III of their motor-sensory shortcomings, aggravate and underpin the stigma of being disabled, and thus threaten their identity as 'normal'. Similar findings are described in a study of community-living older people.<sup>38</sup>

## 5.4 FALL RISK AND RISK FACTORS

The participants considered falls to be a part of their life, corresponding to findings in individuals with cerebral palsy.<sup>122</sup> The ability to walk was of prime importance to the participants, despite the fact that this ability implied an increased risk of falling, fall-related concerns, embarrassment and injuries. This is in line with the preferences described by individuals with SCI in other studies.<sup>19,123</sup> Falling was often perceived as a symbol of losing control of oneself and seemed to challenge the participants' desire to maintain a normal, healthy and well-functioning identity in every respect. Similar findings have been described in community-living older people and in individuals with cerebral palsy, where the feared consequences of falling were linked to social embarrassment and indignity, with consequent damage to personal confidence and identity as well as physical harm and disability.<sup>38,122</sup> Despite this threat, the informants in Study III often reported a willingness to operate at the limits of their functional ability and risked falling in activities that were important to maintaining their self-image as normal. Their viewpoints appeared to be the same as the mountaineer's: One should try to minimise risks but accept that there will always be a risk, which is justified by the goal.

In order to prevent falls and minimize fall risk in ambulatory individuals with SCI, there is a need to explore risk factors as these have not yet been established for this group. Compared to wheelchair users, ambulatory individuals had higher odds of reporting recurrent falls (Study I). This is in line with previous research, where wheelchair users reported fewer falls than ambulatory individuals.<sup>3,5,7,10,11,37,48</sup> Sitting implies a greater base of support and a lower centre of body mass compared to standing, which may decrease the risk of falling in wheelchair users. Higher functional ability, as measured by the ability to get up from the ground by oneself and to perform regular exercise, was associated with recurrent falls, which is in line with other studies.<sup>6,11</sup> In addition, the ability to get up may lead to a feeling of confidence in coping with a fall, thus increasing the willingness of these individuals to accept greater risks of falling. Unlike other studies, younger age was associated with recurrent falls.<sup>11,14</sup> Adults, compared to the elderly, may be more physically challenged since they may still be working (45% in this

sample) and may perform more physically challenging activities, which could explain this finding.

For the ambulatory group, different factors were found to be associated with recurrent falls in the retrospective (Study I) and prospective (Study II) studies. A small sample size, recall bias and other strong predictors are the most likely explanations for this difference. Reporting previous recurrent falls turned out to be the strongest predictor of recurrent falls. This is in line with findings in several other populations, including the elderly and individuals with PD.<sup>124,125</sup> Previous falls is used as one of the predictors in fall-risk screening tools for these populations.<sup>124,126,127</sup> Similar to Phonthee et al.,<sup>7</sup> we found that fear of falling was a predictor of recurrent falls. Fear of falling assessed with a single item question, remained significant through the multiple logistic regression analysis. This indicates that the question can be used to identify recurrent fallers among ambulatory individuals with SCI. Although a somewhat weak predictor, individuals with a slower maximal walking speed tended to fall more. When regarding this test as a proxy for lower levels of physical functioning, it is consistent with a later study by Phonthee et al.,<sup>7</sup> but contrary to the findings in other studies,<sup>6,8,37</sup> where higher levels of functioning were associated with falls. Different methods for measuring physical functioning as well as sample differences may explain this discrepancy. It has also been suggested that there is a non-linear relationship between physical functioning and falls, where individuals with either low or high function have an increased risk of falling, which may explain these contradictory findings.<sup>12</sup>

## **5.5 FALLS AND BALANCE CONTROL**

Although the participants perceived a loss of balance as the main cause of many falls, no association between the BBS and recurrent falls was found. However, there was a significant negative correlation between the BBS and the number of prospectively reported falls, implying that those with poorer balance fell the most, although the correlation was low. There was a considerable ceiling effect, and thus a low sensitivity of the BBS in the cohort of Study II. This is a known disadvantage of the BBS in populations with relatively good walking ability. In order to capture the variety of balance control in ambulatory individuals with chronic SCI, a more sensitive balance scale with a lesser ceiling effect is needed. The Mini-BESTest proved to be better in these respects, although no association with recurrent falls could be found (Study IV).

Researchers has pointed out that there is no straightforward relationship between functional ability such as balance control and falls.<sup>6,128</sup> Reduced balance can be moderated in several ways,



i.e. using walking aids<sup>129</sup> or through self-inflicted activity restrictions. Some participants in our studies used a wheelchair for mobility outdoors while others used a walker instead of crutches, thus lowering fall risk. The correlation between falls and balance control may also be lower in an SCI cohort than in the elderly or individuals with PD. The SCI population distinguishes itself from these populations with a higher proportion of males who take more risks and also show less concern about falling compared to women<sup>130</sup> also shown in Study III. Further, the SCI population is younger with a mean age around 45 years<sup>2,28,30</sup> and may therefore be willing to accept greater risks of falling.

## **5.6 METHOLOGICAL CONSIDERATIONS**

### **5.6.1 Sample representativity**

The generalizability (external validity) of depends on the representativity of the population studied. The samples in Study I, II and IV were derived from a 12-month cohort attending regular check-ups in connection with lifelong follow-up at SunRH and Rehab Station/Spinalis. Although the follow-up program is offered to all patients, there is a risk that individuals with no perceived problems or with severe psychosocial problems or co-morbidities have been less likely to participate. Nevertheless, the low percentage (5–10%) of individuals declining participation improves the chance of having included a representative sample. Additionally, there were no significant differences in age, gender, time post-injury and/or level and extent of injury between the participants and those who declined participation or were excluded.

### **5.6.2 Sample sizes**

The SCIP FALLS Study intended to include 200 individuals, with approximately 50 per cent walking and 50 per cent wheelchair users. However, although 224 individuals were included, only 73 (33%) were classified as ambulatory. Thus, our estimated percentage of ambulatory individuals turned out to be too high. There was a higher percentage of ambulatory individuals in the Norwegian cohort (42%) than in the Swedish cohort (25%). Individuals in the Swedish cohort had been injured for a somewhat longer period of time (median 16 years, Q1–Q3: 8–28) compared to the Norwegian cohort (median 12 years, Q1–Q3: 5–24). A couple of decades ago, the proportion of individuals with complete SCI was higher, and as Rehab Station/Spinalis has had its regular follow-up program for a longer period than SunRH, this may explain some of this discrepancy.<sup>1,2</sup> The small sample sizes have given little power for finding associations with predictors for recurrent falls in studies I and II, and thus the results must be interpreted with caution.

### 5.6.3 Methods

The methods used in this thesis have strengths and limitations. Important strengths are the face-to-face baseline data collection done by two investigators including physical assessments, and the rigorous follow-up of falls and fall-related injuries. The great variety of methods such as interviews, assessments and questionnaires can also be considered a strength as similar variables could be cross-checked. In additions, instruments that were validated for the SCI population were used whenever possible. However, most were validated for similar populations.

We did consider using falls as a continuous variable, similar to Wirz et al.<sup>10</sup> However, as we suspected a great variation in the number of falls with potential outliers, and as the research on falls has almost exclusively used falls as a dichotomous variable, we decided to use falls as a dichotomous variable despite the obvious loss of information. The cut-off for falls was discussed extensively in the SCIP FALLS Study group. Three alternatives used in neurological populations were considered: 0/1 falls,<sup>5,7,131</sup> 0–1/>1 falls<sup>132</sup> and 0–2/>2 falls.<sup>133,134</sup> The registration periods as well as the methods used in these studies vary considerably. Our clinical experience along with the scarce literature available on falls in this population when planning this study ruled out 0/1 as a sensible cut-off since the fall incidence in general would be high. We calculated that with a cut-off of 0–2/>2 falls, approximately 50 per cent of the participants would report recurrent falls retrospectively, which would maximise the statistical power. Further, the 12-month registration period contributed to the selection of 0–2/>2 as the cut-off due to the presumed high fall-incidence.

Fall recording periods vary across studies, which makes comparisons of fall incidences difficult. The ProFaNE consensus<sup>35</sup> recommends a 12-month registration in intervention studies, but there is no consensus regarding the length of recording periods in incidence studies. There may be reasons to choose a shorter registration period than 12 months i.e. participant compliance and financial reasons. No other study in the SCI population has used the same cut off for recurrent falls (>2) in combination with a 12-month recording period. To make such comparisons, additional analysis has been provided in this thesis. In Study II the 12-month fall incidence was 84 per cent. After 6 months 71 per cent of the participants had fallen at least once. Thus, it is evident that a 12-month incidence is not the same as two times the six-month incidence when the cut-off is 0/1 fall. The same applies for recurrent falls, although the difference was a little less (35% at 6 months and 48% at 12 months). This discrepancy may especially be true for populations with a high proportion of recurrent fallers.

The number of falls reported retrospectively was significantly higher than the number of prospectively registered falls. This is in contrast to findings for the elderly, who are known to

under-report falls in retrospective studies.<sup>135</sup> We assume that under-reporting in the prospective part is low due to the rigid follow-up system. Thus, recall bias when estimating falls that have occurred in the previous year seems to be the most probable explanation. It should be mentioned that the retrospective reported and prospectively registered falls represent different years, so there may in fact also be a real difference in the number of falls. However, a Hawthorne effect and the rigorous follow-up might have reduced the number of falls registered in the prospective study.<sup>136</sup> This tendency was confirmed by several participants, who expressed the desire to report no falls, and thus might have been more cautious in everyday life, thereby reducing their number of falls.

Injury severity was self-reported within the taxonomy proposed by Schwenk.<sup>36</sup> Fractures were verified by thorough descriptions of fracture-related procedures during the telephone interview. Reports on fall-related injuries in SCI populations differ,<sup>5,7,9-11,14</sup> but most studies report fracture incidence. According to the PROFaNE consensus,<sup>35</sup> the peripheral fracture rate, verified using radiological evidence, is the only robust and feasible measure of injury in the elderly. Moreover, drawing a distinction between major and minor soft tissue injuries has been problematic, and the self-reporting of injury can be inaccurate. For individuals with SCI, it is also important to report soft tissue injuries as such injuries can be harmful, worsen and lead to increased disability because of the SCI. Hence, there is a need to standardise the reporting of soft-tissue injuries.

The single item question on fear of falling, which was a predictor of falls and injurious falls in Study II, includes emotional as well as behavioural aspects and might therefore be interpreted in different ways by the individuals.<sup>44</sup> The question has been criticised for a lack of sensitivity, and the test-retest reliability has been low to moderate<sup>45</sup> and also needs to be studied in the SCI-population. In this thesis significantly less reported fear of falling at 12-month follow-up compared to baseline. An explanation of this finding may be that there were fewer participants at the 12-month follow-up and that the question was answered under two different circumstances; in a hospital setting at baseline and at home at follow-up which may have influenced the answers.

Different variables were associated with recurrent falls in studies II and III. There were fewer recurrent fallers as well as some dropouts in the prospective study that may have contributed to these differences. The ability to get up from the ground, a factor associated with recurrent falls in the retrospective study, might indicate a higher level of functioning and thus a willingness to take more fall risks. However, in the prospective study, a slower maximal walking speed predicted recurrent falls, which points in the opposite direction. A suggested non-linear relationship between physical functioning and falls, where individuals with either low or high function have an increased risk of falling, may explain these contradictory findings.<sup>12</sup> Different cut-offs for fear of

falling were used in the retrospective (Study I) and prospective (Study II) studies, which might have affected the logistic regression models. However, when applying the cut-off used in the prospective study, it did not turn out to be a factor associated with recurrent falls in the retrospective study.

Risk-taking behaviour is a common cause of SCI,<sup>90</sup> and may be a confounder for fall risk behaviour after injury. We were not able to capture such behaviour in a satisfactory manner. The three risk questions used in this thesis were more appropriate for youth, for whom they were originally designed, and less appropriate for a somewhat older sample. Another potential confounder that was verified in the qualitative study (Study III) was that falls, as a cause of SCI, may affect fall risk behaviour after the injury.

#### **5.6.4 Trustworthiness**

In qualitative research, the aim of trustworthiness is to support the argument that the findings are 'worth paying attention to'.<sup>137</sup> According to Elo et al.<sup>137</sup> this is especially important in studies utilising inductive approaches, such as Study III, where categories are created from raw data without a theory-based matrix. Trustworthiness is often divided into four aspects: credibility (equivalent to internal validity), transferability (equivalent to external validity), dependability (equivalent to reliability) and confirmability (equivalent to objectivity).<sup>138</sup>

Credibility was ensured by the transparency of the data collection and analytic processes. The semi-structural interview guide that was employed kept the focus on experiences and perceptions of falls and fall risk. However, this may also have posed a limitation in aspects not considered by the research-team. For example, answering a questionnaire before the interview could have added to the informants' pre-understanding of the subject matter. The informants may also have been influenced by the fact that the interviewer was a physiotherapist, whose role is to train and challenge gait and balance control with the aim of enhancing physical function and decreasing fall risk.

To support transferability, a purposive sampling was done and a good description of the informants provided. A couple of factors may have affected transferability: the percentage of women was somewhat higher (33%) than in the SCI population as a whole (approximately 20%), although the percentage of ambulatory women in the SCI population is unknown. This may have led to overemphasising aspects that were only mentioned by women. In addition, a fairly high percentage of the informants reported regular fitness training compared to another study of a similar population,<sup>139</sup> which may have had implications on their perceptions of falls and risk of

falling. It is also a limitation that all informants had fallen the previous year, as near falls or a lack of falls can influence perceptions of falls and risk of falling.

Dependability was ensured through the first author doing all the interviews using a semi-structured interview guide. The interviews were transcribed when all interviews were done, and the analysis process was completed within a limited period of time, thus minimizing instability of the data.

Confirmability was addressed by taking steps to ensure that the findings reflected the informants' perceptions and not those of the researcher. The researchers' pre-understanding of the concepts of interest was written down before the interviews were performed, and the researchers discussed their predispositions during the analysis process.



## 6 CLINICAL IMPLICATIONS

Physical activity is important for health and well-being as well as for preventing decline of function in individuals with SCI. Being physically active will always imply some fall risk. However, somewhere along the line there are individual trade-offs for when falls become a problem and preventive means should be considered.

Clinicians need to be aware that most individuals with SCI are at risk of falling and that fall incidence in ambulatory individuals is high compared to non-disabled healthy individuals. As the mean age in the SCI population is increasing and falls is the leading cause of injury, and as more individuals remain ambulatory, clearly, prevention measures should be initiated both during rehabilitation and during the lifelong follow-up.

Informing patients about their fall risk and providing them with possible means that can reduce their risk is the responsibility of the clinicians. Risk awareness and risk willingness should be addressed during rehabilitation as well as at follow-up, taking into account the cultural context and the wide range of perceptions of falls and fall risk. Falling technique and the ability to get up after a fall should probably be practiced when applicable to reduce injurious falls as well as concerns about falling.

Preventive measures should especially target individuals at risk of injurious falls and other adverse consequences of falls. A few individuals have dysfunctional fall-related concerns. Such excessive concerns should be revealed, taken seriously and may be managed with cognitive behavioural interventions.

Both the BBS and Mini-BESTest proved to be valid scales for assessing balance control. The Mini-BESTest appeared to be the preferable instrument for ambulatory individuals with moderate and good walking ability due to its lack of a ceiling effect, better sensitivity and better scaling properties. However, in individuals with poorer walking function, the BBS may be a better choice.





## 7 FUTURE DIRECTIONS AND RESEARCH

### 7.1 PREVENTIVE MEASURES

Considering the high incidence of falls and fall-related injuries, there is a need for preventive strategies in ambulatory individuals with SCI. A number of body structures are involved in balance control and are to some extent amenable to interventions or compensatory strategies. However, how to prevent falls and fall-related injuries in the SCI population is not known, although studies of other populations may provide some guidance. The large age span and the multifactorial nature of falls calls for culturally adapted programs targeting individual needs. There is a demand for multifactorial interventions, including education about fall prevention,<sup>109,140,141</sup> although this has to be due to further research.

#### 7.1.1 Exercise interventions

Exercise interventions have proven to be effective in reducing falls in the elderly<sup>109,140</sup> as well as in other groups with elevated fall risk.<sup>142,143</sup> They may also have an impact on the fear of falling, at least temporarily reducing this fear by enhancing confidence in balance control.<sup>46</sup>

Muscle strength is an important determinant in the occurrence of falls, the direction of falls and of the efficacy of protective responses.<sup>144</sup> Thus increasing muscle strength may reduce falls and their impact. Despite the fact that individuals with chronic incomplete SCI have compromised neuromuscular systems, recent research shows that there is a reserve of force-generating capability that may respond to training.<sup>145</sup>

Balance training seems to improve balance,<sup>142,143</sup> also in individuals with chronic SCI<sup>146</sup> and may have an impact on fall-related concerns.<sup>147</sup> However, improvements will probably mainly be in trained tasks.<sup>148</sup> Consequently, the specific task that needs improvement should be trained.

Falls will always happen, but it is essential to avoid injurious falls. Learning falling techniques, for example, through martial arts fall training may decrease the impact of falls<sup>149-151</sup> and could be an option in injury prevention.

#### 7.1.2 Intervention targeting single risk factors

There are several single fall-related risk factors that may be targeted. As in the elderly population,<sup>109</sup> a medication review and cataract removal are probably appropriate interventions. Podiatry interventions such as optimising footwear may also reduce risk of falls,<sup>152</sup> since paresis in the foot and leg muscles as well as decreased sensibility, affecting balance control is a common

problem. Walking aids can reduce as well as increase fall incidence and should thus be reviewed regularly. Vitamin D supplementation has shown some preventive effects on falls in the elderly<sup>109</sup> and in stroke patients<sup>153</sup> with low vitamin levels. As many individuals with SCI also have low vitamin D levels,<sup>154</sup> this may be an option in this group as well. Pharmacological therapy targeting osteoporosis may be considered as a partial strategy for preventing fractures,<sup>155</sup> especially in postmenopausal women with an increased fall risk.

## **7.2 SUGGESTIONS FOR FURTHER RESEARCH**

Our prediction models showed that fall history, fear of falling and walking speed could predict recurrent and injurious falls. However, these findings need to be verified in larger cohorts.

The variation in fall monitoring and reporting found in the research literature makes comparison between studies difficult. There is a need to standardise the monitoring periods along with the cut-offs for falls in populations under the age of 65. A definition of recurrent/frequent fallers needs to be established.

There is also a need to standardise the reporting of fall-related injuries. The taxonomy proposed by Schwenk et al. may provide a starting point. The psychometric properties of such an instrument need to be established.

Psychometric testing of certain assessments instruments, i.e. fear of falling and Fall Efficacy Scale International, needs to be conducted in the SCI population.

Given the choice of both Berg Balance Scale and Mini-BESTest as measures of balance control, especially in rehabilitation settings, there is a need to establish a cut-off score in order to determine when to use either of the scales.

Finally, there is a need to develop and test prevention strategies built on the prediction models in longitudinal studies.

## 8 CONCLUSION

Most individuals with SCI should be considered at risk of falling, wheelchair users as well as ambulatory individuals. Ambulatory individuals had a high risk of falling, as a vast majority of the participants fell at least once, and around half reported recurrent falls during a 12-month registration period. More than half reported an injurious fall, although the majority of these falls only caused minor injuries. Three ambulatory individuals reported serious injuries (fractures), a rate that is comparable to serious injuries in elderly. A history of recurrent falls and fear of falling could predict recurrent and injurious falls in the ambulatory individuals. In addition slower maximal walking speed was a predictor of recurrent falls. However, further studies with larger sample sizes are needed to validate these findings.

Falls were considered to be a part of life by the ambulatory individuals, but the falls interfered with their identities and self-images as normal, healthy, and well-functioning. Perceptions of falls, fall risk and fall-related injuries seemed to be based both on trying to minimise fall risk and concerns and on the willingness to increase fall risk in order to maintain an identity as normal. A few individuals expressed inexpedient fall-related concerns, and interventions should target these concerns.

The BBS and Mini-BESTest are both valid balance scales for individuals with chronic SCI. The Mini-BESTest appears to be the preferable scale for ambulating individuals due to its lack of a ceiling effect, better sensitivity and better scaling properties. However, in individuals with poor walking ability, the BBS may be a more appropriate choice.

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