

Stem cell tourism and spinal cord injury in South Africa

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Background. The publicity around stem cell therapy has given many persons who have sustained a devastating injury such as spinal cord injury (SCI) the hope of achieving partial or full recovery from their injuries. Several phase I and II clinical trials are being conducted owing to positive results obtained in animal models. While safety during the trials has been demonstrated, clinical efficacy in the outcome of ethically approved trials is still lacking. Many persons affected by SCI are, however, desperate for a cure and are lured into undergoing stem cell therapy by marketing campaigns and information readily available on the internet. These people travel far and wide to undergo stem cell therapy, which has led to the term 'stem cell tourism'.

Objectives. To compare the data from participants' self-report questionnaires before and after their stem cell therapy to determine if there were differences in their functional and neurological status, and to record details of the procedures.

Method. Persons who sustained a SCI and who received apparent stem cell therapy in South Africa (SA) or elsewhere were recruited to participate in the present study. Volunteers who gave written informed consent were asked to complete a biographical questionnaire and validated self-report questionnaire (Spinal Cord Independence Measure version III (SCIM III)) before and after their stem cell therapy to determine if there were differences in their functional and neurological status. The results of the self-report questionnaires were compared with the published expected functional outcome of people with lesions at a similar level of SCI to the participants. The secondary aims of the study were to document details of the procedures and their locations, the sources of 'stem cells' and the cost.

Results. There was no indication that the participants' functional outcomes, as measured by the self-reported SCIM III, were better than the expected level of functional ability in patients with similar injury levels. Likewise, the neurological motor recovery scored on the International Standards for the Neurological Classification of Spinal Cord Injury (ISNCSCI) motor scores showed no improvement post stem cell therapy.

Conclusion. This study highlights the need to curb the practice of offering unethical and non-evidence-based stem cell therapy for SCI. Ethical research and treatment is encouraged as well as an effective legal framework and education of health professionals, patients and their family members and caregivers, which will avoid unrealistic expectations, bogus therapies and the potential adverse effects of non-evidence-based 'stem cell therapies' offered by clinics via the internet.

S Afr Med J 2019;109(8 Suppl 1):S18-S24. <https://doi.org/10.7196/SAMJ.2019.v109i8b.13824>

The worldwide prevalence of spinal cord injury (SCI) is estimated to be in the range of 223 - 755 per million inhabitants.^[1] The incidence of SCI is estimated to be 40 - 80 new cases per million per year. Between 250 000 and 500 000 people around the world are afflicted with a SCI every year.^[2]

In South Africa (SA), the incidence of SCI is estimated to be 104 per million inhabitants,^[3] which is well above the global incidence. In 2017, the incidence in Cape Town was reported to be 75.6 per million persons, with the main aetiology being assault, followed by motor vehicle accidents (MVAs).^[4] Another study in Cape Town reported MVAs to be the major cause of SCI.^[5]

The primary aim of the healthcare team managing patients with SCI is to reduce mortality and morbidity, including complications, and to reduce the burden of care by improving patients' functionality and independence.^[6,7] The standard principles of treatment of a person with SCI entail stabilisation of the injury, prevention of secondary injury, surgical decompression and fusion, and rehabilitation.^[8] Impairments following SCI are loss of motor, sensory and autonomic function, including bladder, bowel and sexual function,^[8,9] leading to loss of participation in normal life activities. These impairments are the result of damage to spinal cord axons, loss of neurons, the activation of astrocytes and microglia and demyelination and degeneration of oligodendrocytes and scarring.^[10-13]

Stem cell technologies have opened up the possibility of a potential cure for SCI based on the positive motor and functional improvements seen in pre-clinical rodent models with spinal cord injury.^[13-16] Stem cell transplantation in patients with SCI aims to replace impaired neurons and oligodendrocytes, to provide trophic support for existing (possibly ischaemic) neurons, and to modify the environment within the spinal cord to facilitate axonal regrowth. Results in pre-clinical studies have begun to translate into human trials, and several scientific and ethically approved trials are underway. Some trials have demonstrated safe procedural administration of stem cells into the spinal cord, i.e. without negative side-effects, but to date neurological recovery has been limited.^[9,13,17,18] This lack of efficacy is likely to be due in part to differences between rodents, larger mammals and humans; the nature of the experimental injury induced v. the actual traumatic incident; the challenges associated with translating basic research findings to the clinic; and insufficient outcome measures being utilised during the research. It is well recognised that the translation process from basic research to the clinic is long and complex.^[13,17-20]

The devastating and debilitating result of SCI motivates survivors to search for new therapies or cures almost on a continuous basis. Following a SCI, these individuals may be willing to pay large sums of money for a cure,^[9] particularly when their rehabilitation

professionals cannot offer the recovery they seek. Clinics worldwide offer cures on the internet for SCI using what are purported to be stem cells.^[13,14,21,22] People with SCI, who are desperate for a cure, are willing to risk money and health to visit these clinics to be cured,^[28] in SA and abroad, resulting in so-called stem cell tourism.^[13,21-28] The interventions^[28] are done at great financial cost, despite the lack of clinical and statistical evidence that substantiates the claims made for a cure. Several organisations have been proactive and invested significantly into public/patient education by publishing position statements, handbooks and guidelines on the lack of research evidence in the use of stem cell therapies for SCI (International Society for Stem Cell Research (ISSCR: <https://www.closerlookatstemcells.org/>) and the International Spinal Cord Society (ISCoS: <https://www.iscos.org.uk/>)). A warning was issued by the ISSCR against the use of unproven stem cell interventions: 'The ISSCR condemns the administration of unproven stem cell-based interventions outside of the context of clinical research or medical innovation compliant with the guidelines in this document and relevant laws, particularly when it is performed as a business activity.' (<http://www.isscr.org/docs/default-source/all-isscr-guidelines/guidelines-2016/isscr-guidelines-for-stem-cell-research-and-clinical-translation.pdf?sfvrsn=4>). Principles of good research, ethical conduct, informed consent and peer review are all noted on the website.

Organisations with educational websites for healthcare professionals treating people with SCI such as Spinal Cord Injury Rehabilitation Evidence (SCIRE:<https://scireproject.com/>), the American Spinal Cord Association (ASIA: <https://asia-spinalinjury.org/>) and ISCoS (<https://www.iscos.org.uk/>), make no reference to stem cell treatment as part of the management of SCI. These websites are updated regularly on the basis of the most recent research evidence. Much research is being conducted but no recommendation on stem cells as a cure for SCI has been forthcoming, as the research is still in an early phase.

Possible complications of stem cell therapy include the risk of tumour growth (especially if pluripotent cells such as undifferentiated embryonic stem cells are used during the procedure)^[12,29] and an increase in neuropathic pain or allodynia as a result of aberrant axonal sprouting.^[13,17]

Objective estimation of a patient's functional recovery after a SCI and the assessment of their functional outcome post rehabilitation are topics addressed extensively in the literature.^[13,30-35] As a reaction to the trend that patients seek stem cell interventions despite the lack of research evidence in humans (including clinical trials that are still in early phases), a survey on persons living in South Africa who had undergone 'stem cell therapy' was undertaken to determine whether the therapy had had an influence on their level of motor impairment and functional ability.^[13,30,36,37] The primary aim of the present study was therefore to perform a critical analysis of the level of motor impairment and functional ability measured on the Spinal Cord Independence Measure (SCIM) III in people with SCI who had undergone 'stem cell therapy'.^[32,33] The secondary aims were to document details of the procedures and their locations, sources of 'stem cells' and cost.

Methodology

Statement of ethical conduct

Approval was obtained from the Research Ethics Committee of the Faculty of Health Sciences, University of Pretoria (ref number S5/2010). Approval from the CEO of the Quadpara Association of South Africa (QASA) was obtained to use their membership email list. Each participant gave written informed consent before completing the questionnaires.

Recruitment

Participants in the survey were recruited from persons with SCI who had received rehabilitation at a well-known rehabilitation centre, where one of the authors (MS) is employed as a physiotherapist and where the participants asked to receive rehabilitation after receiving stem cell therapy. Participants were also recruited from QASA's membership list. Inclusion criteria were: (i) people with SCI living in SA who had received stem cell therapy in SA or abroad; (ii) people with SCI who had received stem cell therapy and who had received their rehabilitation at a rehabilitation centre or unit or practice in SA; (iii) people with SCI who were willing to participate voluntarily in the study and had given their informed consent; and (iv) participants over the age of 18 with SCI and who were otherwise in good health.

All persons with SCI who, after having received stem cell therapy, requested rehabilitation at the rehabilitation centre, gave consent for their data to be used in this research project. QASA members were also emailed and asked to participate in the study if they had received stem cell therapy. Other rehabilitation units throughout SA were asked to recruit volunteers amongst persons who had undergone stem cell therapy. All volunteers who responded were included in the research. Respondents who expressed an interest in receiving stem cell therapy, but had not received any, were excluded from the study.

Participants who volunteered to participate in the study were requested to complete a biographical questionnaire and the SCIM III functional outcomes measure retrospectively after receiving stem cell therapy and subsequent rehabilitation. Participants also had to give permission that their ISNCSCI scores could be accessed from their pre-stem cell therapy patient records at discharge from their initial rehabilitation.

The functional ability of people who sustain a SCI is not accurately estimated by a neurological examination alone;^[36] therefore participants' functional ability was assessed by scoring the activities of daily living using the SCIM III outcomes measure.^[32,33] The SCIM III is a standardised rating scale reflecting the level of independence (participation) in activities of the person with a SCI in daily life such as mobility, self-care, sphincter control and respiratory function.^[32,33,37] In this study, the self-report version of the SCIM III in which participants had to assess their own functional ability, was used. The self-report version of the SCIM III has previously been validated.^[32,33,38] The participants' self-reported SCIM III scores were compared with the published SCIM scores of lesions at various levels of the spinal cord.^[35,36]

Results

Eleven persons with SCI who had received 'stem cell therapy' volunteered to participate in the study (Table 1). Owing to the large differences in the nature of the participants' injuries and the treatments they had received, the results are presented as descriptive statistics.

Participants indicated that their expectation of the stem cell therapy was to gain any improvement in the function that they lost or which had been compromised owing to their SCI. Expectations specifically stated were: higher functional ability related to improvement in hand function, walking, and improvement in bladder and bowel function.

Participants reported that the reason for considering stem cell therapy was based on the positive reports obtained from the internet or from information received from family and friends. Participants received their 'stem cell therapy' between 14 days and

8 years post SCI. The outcomes can therefore not be compared between participants.

The type of stem cell therapy that participants received is displayed in Table 2. The procedure at the various centres consulted

by the participants differed, but all centres recommended at least 3 months of intensive rehabilitation post stem cell therapy.

Participants' self-reported SCIM III scores were compared with the published SCIM III scores of patients with a lesion at the

Table 1. Biographical data of participants

Subject	Age (years)	Gender	SCI type	Cause	Level of injury	Time between SCI and stem cell therapy
1	51	M	Para ASIA A	GSW	T5	5 years
2	36	M	Tetra ASIA A	GSW	C8/T1	8 years
3	39	M	Para ASIA A	GSW	T5	14 days
4	38	F	Tetra ZPP	MBA	C6/7	1 year
5	38	F	Tetra ASIA A	Fall	C4/5	6 years
6	43	M	Tetra ZPP	MVA	C5	7 years
7	42	M	Tetra ASIA A	MVA	C6/7	2 years
8	30	M	Tetra ASIA B	MVA	C6/7	9 months
9	47	M	Para ASIA A	MVA	T12/L1	4 years
10	27	M	Tetra ASIA A	QUAD	C6/7	2.5 years
11	22	F	Para ZPP	QUAD	T5	3 years
					4 - C6/7, 2 - T5	
					1 - C4/5, 1 - C5	
					1 - C8/T1, 1- T12/L1	
Mean = 36.9		8 M 3 F	4 Para 7 Tetra			Mean = 3.6 years

ASIA = American Spinal Injury Association classification for spinal cord injury; Para = paraplegic; Tetra = tetraplegic; T = thoracic; C = cervical; ZPP = zone of partial preservation (muscles and skin innervated below the lesion in the complete SCI); MVA = motor vehicle accident; QUAD = quad bike accident; GSW = gunshot wound.

Table 2. Nature of the stem cell treatment

Subject	Nature of stem cells	Delivery mode	Country of treatment	Pre-stem cell treatment at place of administration	Post-stem cell treatment recommended
1	Autologous	Lumbar puncture	India	Nonspecific	Rehabilitation
2	Sheep	Subcutaneous/intramuscular injection	South Africa	Nonspecific	Rehabilitation, weekly stem cell injection and stem cell tablets
3	Rabbit	Subdural injection during spinal surgery	South Africa	Nonspecific	Homeopathic tablets, rehabilitation
4	Rabbit	Lumbar puncture, injections into abdomen	Germany	Detox, ozone therapy	Rehabilitation, multivitamins
5	Rabbit	Four injections on stomach, one into spinal cord, one on each hip	Germany	One week ozone therapy, Lipoten drip	Rehabilitation, drips, vit B12
6	Sheep	Subcutaneous or intramuscular injections into back and neck	South Africa	Nonspecific	Rehabilitation, weekly injections
7	Unknown	Intravenous injection	Holland	Nonspecific	Rehabilitation
8	Fetal	Intravenously in saline solution. Also injected into subcutaneous tissue around back of neck	Holland	Nonspecific	Physiotherapy and rehabilitation
9	Rabbit	Multiple injections	Germany	Detox and preparation medicine	Rehabilitation
10	Fetal	Lumbar puncture after drainage of syrxin in spinal cord	China	Traditional Chinese medicine, acupuncture, IV drip to boost stem cells	Physiotherapy 2x/day, stretches more than strengthening exercises: arms and legs
11	Fetal stem cells	Lumbar puncture after surgery	China	Traditional Chinese medicine, acupuncture, IV drip to boost stem cells	Physiotherapy 2x/day, stretches more than strengthening exercises: arms and legs, rehabilitation

same level^[35] (Fig. 1). The actual scores are presented in Table 3. In Fig. 1, it can be observed that 6 of the participants had not reached the expected functional level on the SCIM III related to their SCI level

before the stem cell therapy.^[35] Four of the participants' SCIM III scores remained unchanged pre and post stem cell therapy.

Only 1 of the 11 participants exceeded the maximum SCIM III score for her lesion level,

which may be ascribed to zones of partial preservation (ZPP). The same participant's function did, however, not improve after the stem cell therapy and rehabilitation. Based on the qualitative feedback which participants gave, participant no. 11 walked with crutches and an ankle-foot orthosis (AFO) 20% of the time pre stem cell therapy. Post stem cell therapy she had to use a full calliper on her weaker leg owing to diminished sensation and muscle control, and could only walk with a calliper and crutches under supervision for an hour a day. The participant's pain at the level of the lesion improved post stem cell therapy. At the stem cell therapy centre where she received the procedure, she was told that scar tissue was removed during surgery for the stem cell therapy. However, a year following the procedure, the pain had increased to the pre-surgery level.

One participant's SCIM III score (no. 1) decreased by 10 points post-stem cell therapy because he had to change from clean intermittent self-catheterisation (CISC) to an indwelling catheter. One participant's SCIM III score (no. 5) improved by one point during the rehabilitation period post-stem cell therapy and then returned to the lower level of function prior to stem cell therapy, once he was home again. Participant no. 3 underwent his stem cell therapy 2 weeks after his injury and had had no rehabilitation prior to stem cell therapy. Following the rehabilitation programme, he showed a gain in SCIM III score of 36, but did not reach his expected SCIM III score for his lesion post rehabilitation.

Five participants' SCIM III scores improved post stem cell therapy and rehabilitation. Three of these participants sustained C6/7 lesions. Two of the 3 patients, both of whom had ZPP, achieved better than

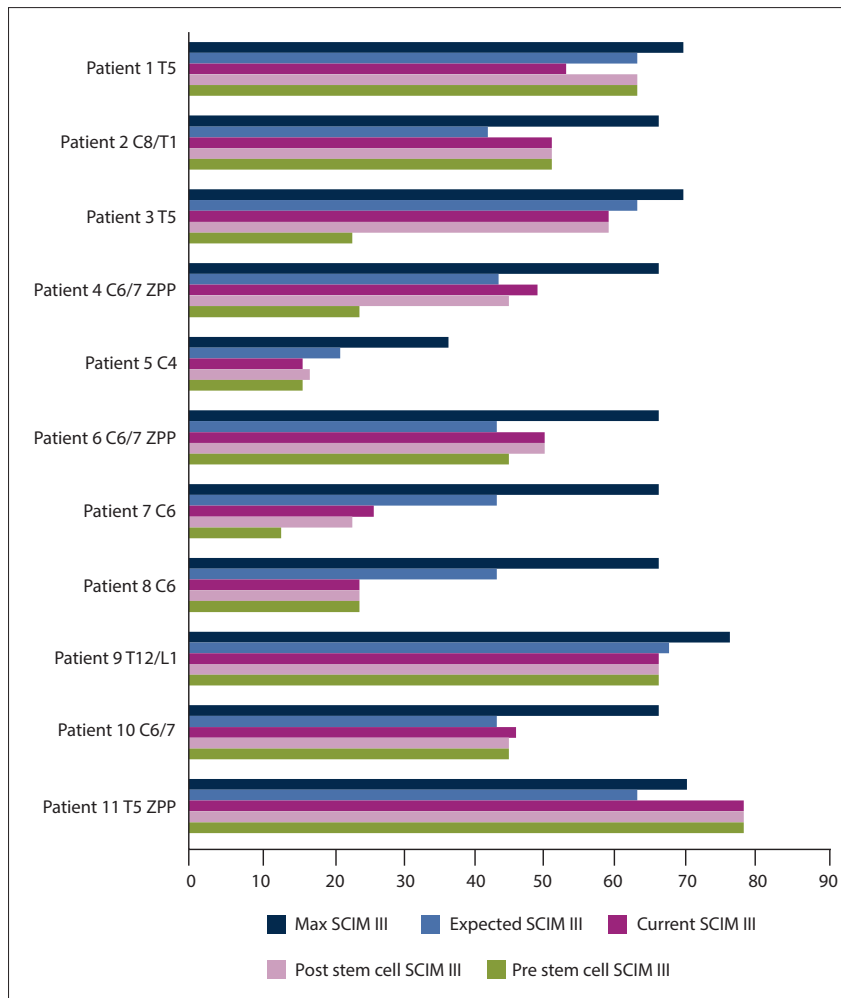


Fig. 1. Comparison of participants' SCIM III scores pre and post stem cell therapy. (ZPP = zone of partial preservation (muscles and skin innervated below the lesion in the complete SCI); SCIM = Spinal Cord Independence Measure.)

Table 3. SCIM III scores in participants' pre- and post-stem cell therapy compared with the functional level of persons with similar spinal cord injuries

Subject no.	Level of injury	Pre-stem cell therapy	Post-stem cell therapy	Current	Expected for injury level ^[37]	Maximum ^[37]	Participant's change in score	Expected change during acute rehab ^[37]	Expected change during post-acute rehab ^[37]
1	T5	63	63	53	63	69	-10	30.5	5.5
2	C8	51	51	51	42	69	0	25	7
3	T5	23 pre rehab	59	59	63	69	36	30.5	5.5
4	C6/7	ZPP	24	45	49	43.5	25	7	7
5	C4		16	17	16	36.5	1	12	0
6	C6/7	ZPP	45	50	50	43.5	5	7	7
7	C6		13	23	26	43.5	13	28	9
8	C6		24	24	24	43.5	0	28	9
9	T12		66	66	66	76	0	34	6
10	C7		45	45	46	43.5	1	7	7
11	T5	ZPP	78	78	78	63	0	30.5	5.5
Average							6	22	6

expected SCIM III scores but did not reach the maximum SCIM III score reported for their lesion level. Five participants achieved higher than expected SCIM III scores but 2 of these (no. 11 and no. 2) had no change in SCIM III score after the stem cell therapy. On average, the participants' SCIM III scores improved by 6 points, which is to be expected during post-acute rehabilitation.^[30,39]

Participants' ISNCSCI motor score changes are presented in Table 4. Four of the 11 participants' ISNCSCI motor scores stayed the same pre and post stem cell therapy. Three participants' scores improved between 2 and 5 scores post stem cell therapy. Reasons for the improvement in ISNCSCI motor scores were ascribed to gains in muscle strength in the muscles that were innervated pre stem cell therapy; no impaired myotomes, pre stem cell therapy, were re-innervated post stem cell therapy. One participant's ISNCSCI motor score decreased by 1 point post stem cell therapy even after rehabilitation. She had to use a calliper instead of just an AFO and crutches post stem cell therapy.

Fig. 2 shows the participants' level of mobility. Of the 11 participants, all used either a power or a manual wheelchair for more than 90% of the time. Two participants used therapeutic walking with assistance and assistive devices but were not functional walkers in their communities. Fig. 3 presents bowel and bladder management post stem cell therapy. All 11 participants had neurogenic bowels

and used a bowel programme, and all except one needed assistance with their bowel programme. Eight participants had indwelling catheters and 3 did CISC, which indicates that none had normal bladder function. These results show no improvement from the pre-stem cell mobility scores.

Participants' financial expenses for receiving stem cell therapy and travel are summarised in Table 5.

Discussion

None of the stem cell treatments advertised to cure SCI resulted in an improvement in function measured on the SCIM III beyond the expected function for the level of injury as measured after traditional recognised rehabilitation programmes, nor did motor scores improve below the pre-

stem cell treatment neurological level of injury. No increased myotome innervation was observed, as shown by the available ISNCSCI motor scores. No change in bladder or bowel function was reported, nor did the participants' mobility improve. The improvement experienced by the participants was most likely brought about by the rehabilitation given post stem cell therapy and not by neural regeneration. Six of the 11 participants had not reached the expected level of functional outcome for the level of their lesions. Post stem cell therapy results such as loss of sensation, increased pain, decreased function, and increased use of assistive devices are not indicative of effective therapy. These results may in fact reflect a detrimental effect owing to the stem cell therapy received.

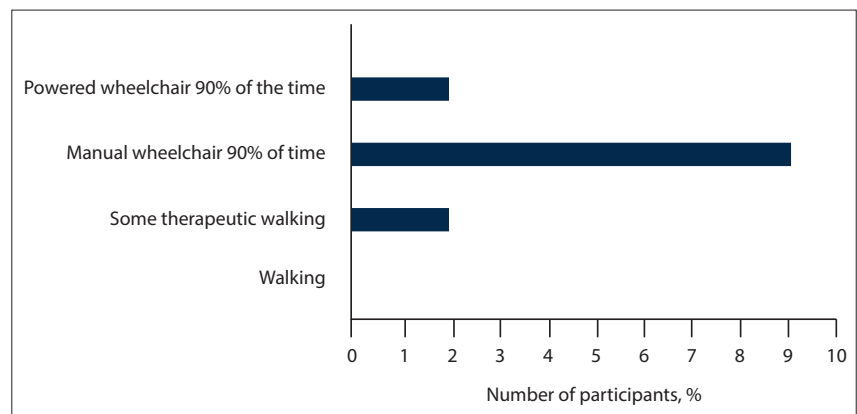


Fig. 2. Mobility outcomes.

Table 4. Muscle strength and changes in ASIA scores

Subject	Pre stem cell therapy – ASIA	Post stem cell therapy – ASIA	Any gain in muscle innervation post stem cell therapy?	Participant's perception of new muscle strength post stem cell therapy	Current problems post stem cell therapy
1	50	50	No	Not stronger	Went from self catheterisation to suprapubic catheter Severe neurogenic pain and constipation
2	44	44	No	Not stronger	Spasms
3	50	50	No	Not stronger	None
4	22	27 no new myotomes	No	Yes, stronger from rehab	
5	6	8	No	Yes, stronger from rehab	Severe neurogenic pain in hands, spasms
6	None	No better	No	Not stronger	
7	None	No better	No	Not stronger	Lioresal pump for spasm
8	None	No better	No	Not stronger	
9	50	50	No	Yes, stronger from rehab	
10	20	24 no new myotomes	No	Yes, stronger from rehab	Spasms and neurogenic pain
11	62	61	No, and loss of sensation	Now needs calliper instead of AFO to walk	Unable to walk as well post stem cell therapy owing to decreased sensation

ASIA = American Spinal Injury Association classification for SCI; AFO = ankle-foot orthosis.

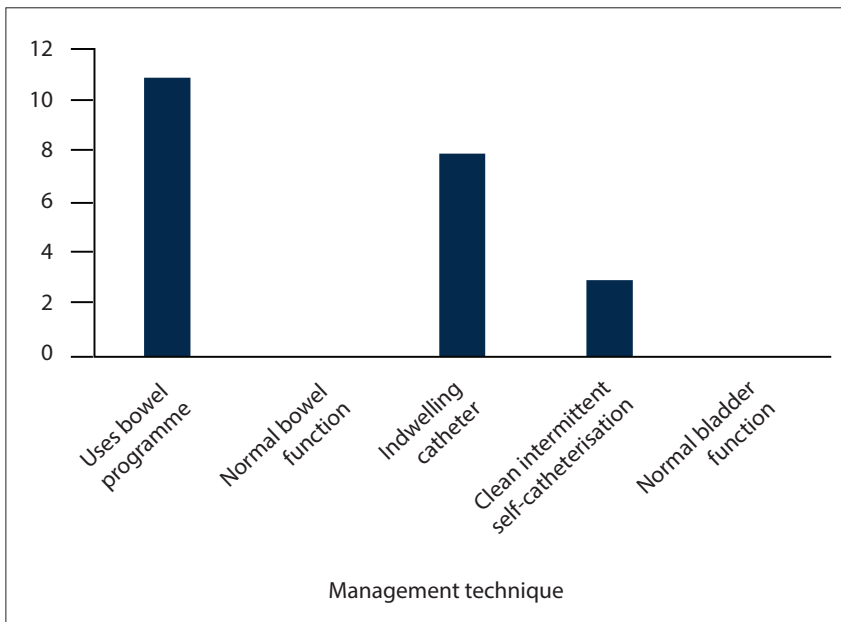


Fig. 3. Bladder and bowel management.

Table 5. Financial cost incurred by participants who received stem cell therapy

Subject no.	Cost of stem cell therapy (ZAR)	Cost of travel (ZAR)	Total treatment cost (ZAR)
1	150 000	36 000	186 000
2	Free	Not specified	N/A
3	150 000	60 000	210 000
4	80 000	89 000	169 000
5	86 200	93 220	179 320
6	Free	11 200	11 200
7	76 000	71 000	142 000
8	70 000	25 000	95 000
9	150 000	Not sure	150 000
10	650 000	50 000	700 000
11	325 000	71 000	396 000
Total	1 737 200	506 420	2 238 520
Average	157 927	56 268	203 501

Ethically approved and scientific evidence-based trials are being conducted to assess safety and changes in functional ability post SCI, but most are phase I and II trials.^[12,13,18] Before stem cell therapy can become a recognised form of treatment for SCI, the outcome of well-controlled clinical trials is awaited, and the use of unproven therapies such as those reported herein, are discouraged.^[13,28]

The stem cell treatments received, both within SA and abroad, were not administered by recognised spinal cord injury treatment centres or recommended by such, and were all sourced via the internet or by word of mouth from other patients and their families. The stem cell tourism trend^[13,22,27,28] shows that vulnerable people with SCI are willing to undergo non-evidence-based procedures in the hope of achieving a cure. Using the keywords ‘Stem cells for SCI, a

Google search on 8 October 2018 resulted in 8 080 000 hits. ‘Stem cell therapy’ websites are found to be anecdotal in nature, with questionable scientific credibility.^[13,28] As stem cell therapy is still in the experimental phase, it should only be administered as part of a recognised, ethically approved clinical trial, and it should not require that participants pay for the procedure.

The costs incurred as a result of the stem cell therapy and travel, with no clinical evidence of improvement, raises ethical concerns regarding people who are in a vulnerable state being susceptible to emotional and financial exploitation. The ISSCR task force has developed the Guidelines for the Clinical Translation of Stem Cells (<http://www.isscr.org/docs/default-source/all-isscr-guidelines/guidelines-2016/isscr-guidelines-for-stem-cell-research-and-clinical-translation>.

[pdf?sfvrsn=4](#)). This document highlights the core principles that should guide the responsible translation of basic stem cell research into appropriate clinical applications. The dangers of using non-evidence-based stem cell treatment are summarised on the ISSCR website as follows: ‘The premature commercialization of unproven stem cell treatments, and other cell-based interventions inaccurately marketed as containing or acting on stem cells, not only puts patients at risk but also represents one of the most serious threats to the stem cell research community, as it may jeopardize the reputation of the field and cause confusion about the actual state of scientific and clinical development. Government authorities and professional organizations are strongly encouraged to establish and strictly enforce regulations governing the introduction of stem cell-based medical interventions into commercial use.’

The International Campaign for Cure for Spinal Cord Paralysis (ICCP) has compiled guidelines to enable people with SCI who consider participation in clinical trials to make an informed decision regarding stem cell therapy.^[30] The ICCP position statement on cell-based therapies warns people of the risks of partaking in non-evidence-based therapies, both for the sake of the participant and for the future of research in the field. Participation in a clinical trial without ethical approval could limit or disqualify the participant from participating in future ethically approved trials.

In the critical analysis of the outcomes of persons who received stem cell therapy after a SCI, there is no evidence that any of the so-called stem cell procedures that participants underwent were beneficial. With regard to the participants who did experience an improvement in muscle strength and function, this appeared to be in muscles that were innervated prior to the therapy, as a result of neural plasticity and compensation from the rehabilitation, rather than restoration of spinal cord function.^[40] People with SCI should therefore be warned that bogus therapies^[41,42] exist and should be discouraged from undergoing treatment with these therapies after sustaining a SCI.

Regarding the legislation that deals with stem cell therapy,^[43] Chapter 8 of the National Health Act (no. 61 of 2003),^[44] the Medicines and Related Substances Act (no. 101 of 1965),^[45] the Consumer Protection Act (no. 68 of 2008)^[46] and the Health Professions Council of South Africa’s ethical codes regarding good practice, over-servicing, perverse incentives and related matters as well as biotechnology research^[47] are available to all health professionals and

regulators. No action has thus far been taken against professionals providing unproven stem cell treatments to persons with SCI in SA.

Limitations of the present study include the small number of voluntary participants that could be recruited. This may be due to the fact that participants did not want to reveal the cost and poor outcomes of their stem cell therapy. Since this study was concluded, the first author has encountered additional persons with SCI who have undergone stem cell therapy in SA, with a similar lack of positive results.

This study underlines the need for effective legislation and an effective means of law enforcement to guard consumers against exploitation by providers of non-evidence-based therapies. An information booklet compiled by Master *et al.* can be downloaded to assist people who have sustained a SCI, and their families and friends, regarding stem cells and their use (http://www.amc.edu/academic/bioethics/documents/SCPatientBookletFeb_2014.pdf).^[28]

Declaration. This work was submitted for MS's MPhysT degree.

Acknowledgements. None.

Author contributions. MS co-conceived the study, collected data, wrote the first draft of the manuscript and edited subsequent drafts. CAE provided co-supervision, oversaw the collection of data, and edited the manuscript. MSP co-conceived the study, provided supervision, oversaw the collection of data, and edited the manuscript.

Funding. None.

Conflicts of interest. None.

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