Community-based interventions to prevent serious complications and premature death after spinal cord injury in Bangladesh

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BPT (Physiotherapy), MPT (Physiotherapy), MPH (Public health)

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John Walsh Centre for Rehabilitation Research
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Candidate's statement

I Mohammad Sohrab Hossain, hereby declare that this submission is my own work. This thesis does not contain material that has been accepted for the award of another degree.

I Mohammad Sohrab Hossain understand that, if I am awarded a higher degree for my thesis entitled "*Community-based interventions to prevent serious complications and premature death after spinal cord injuryin Bangladesh*" being lodged herewith for examination, the thesis will be lodged in the university library and will be available immediately for use. I agree that the university librarian (or in the case of a departmental library, the head of department) may supply a photocopy or microform of the thesis to an individual for research or study or to a library.

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Supervisors' statement

As supervisors of Mohammad Sohrab Hossain's doctoral work, I certify that I consider his thesis "*Community-based interventions to prevent serious complications and premature death after spinal cord injury in Bangladesh*" to be suitable for examination.

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Authorship attribution statement

The work presented in this thesis was carried out by the candidate under the supervision of Professor Lisa Harvey, Professor Rob Herbert, Professor Ian Cameron and Dr Hueiming Liu. The candidate's contributions for the publications in this thesis are as follows:

Chapter 3: A prediction model to identify people with spinal cord injury who are at high risk of dying within five years of discharge from hospital in Bangladesh. Mohammad Sohrab Hossain, Lisa A. Harvey, Md. Shofiqul Islam, Md. Akhlasur Rahman, Joanne V. Glinsky, Robert D. Herbert. Spinal Cord (2019) 57:198–205.

I have made following contributions for this publication:

- Conception and design of the research including literature search
- Collection of data
- Analysis and interpretation of the findings
- Writing the manuscript, critical appraisal of content and response to reviewers

Chapter 4: Health status, quality of life and socioeconomic situation of people with spinal cord injuries six years after discharge from a hospital in Bangladesh. Mohammad Sohrab Hossain, Md. Shofiqul Islam, Md. Akhlasur Rahman, Joanne V. Glinsky, Robert D. Herbert, Stanley Ducharme, Lisa A. Harvey. Spinal Cord (2019) 57:652–661.

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Chapter 5: Community-based interventions to prevent serious complications following spinal cord injury in Bangladesh: the CIVIC trial[1] statistical analysis plan. Robert D. Herbert, Lisa A Harvey, Mohammad S Hossain, Md. Shofiqul Islam, Qiang Li, Laurent Billot and The CIVIC Trial Collaboration. BMC Trials (2019) 20:238.

I have made following contributions for this publication:

- Conception and design of the statistical analysis plan
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Chapter 6: Protocol for process evaluation of CIVIC randomised controlled trial: Community-based interventions to prevent serious complications following spinal cord injury in Bangladesh. Mohammad Sohrab Hossain, Lisa A Harvey, Hueiming Liu, Md. Shofiqul Islam, Md. Akhlasur Rahman, Stephen Muldoon, Fin Biering-Sorensen, Ian D Cameron, Harvinder S Chhabra, Richard I Lindley, Stephen Jan. BMJ Open 2018;8: e024226. doi:10.1136/bmjopen-2018-024226.

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- Writing the manuscript, critical appraisal of content and response to reviewers

Chapter 7: Loss of work-related income impoverishes people with spinal cord injury and their families in Bangladesh. Mohammad Sohrab Hossain, Lisa A. Harvey, Md. Shofiqul

[1]The acronym CIVIC is used to refer to the trial titled:Community-based InterVentions to prevent serIous Complications following spinal cord injury in Bangladesh.

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Chapter 8: Understanding how a community-based interventions for people with spinal cord injury in Bangladesh was delivered as part of a randomised controlled trial: a process evaluation. *Hueiming Liu, *Mohammad Sohrab Hossain, Md. Shofiqul Islam, Md. Akhlasur Rahman, Punam D Costa, Robert D Herbert, Stephen Jan, Ian D Cameron, Stephen Muldoon, Harvinder S Chhabra, Richard I Lindley, Fin Biering-Sorensen, Stanley Ducharme, Valerie Taylor, Lisa A Harvey. Spinal Cord, DOI. 10.1038/s41393-020-0495-6.

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- Conception and design of the research including literature search
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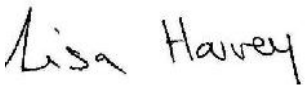
- Analysis and interpretation of the findings
- Writing the manuscript, critical appraisal of content and response to reviewers

In addition to the statements above, in cases where I am not the corresponding author of a published paper, permission to include the published material has been granted by the corresponding author.

Mohammad Sohrab Hossain
August 2020

As supervisor for the candidature upon which this thesis is based, I can confirm that the authorship attribution statement above is correct.



Professor Lisa Harvey
August 2020

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Abstract

Spinal cord injury (SCI) causes serious disability and mortality. Mortality following SCI is higher in low- and middle-income countries (LMICs) than high-income countries (HICs), although accurate data on morality are not yet available from LMICs including Bangladesh. Anecdotal evidence suggests that many people with SCI in Bangladesh die soon after discharge, and those who survive experience life-threating secondary health complications and impoverishment. The most common secondary health complications are pressure ulcers. These are largely preventable and manageable if people have appropriate access to support and advice. Prevention of pressure ulcers and other secondary complications is a better alternativethan treatment for people with SCI in Bangladesh and other LMICs where specialised care following discharge is limited. However, people with SCI need support and adequate knowledge following discharge about self-care management to prevent and manage their complications.I proposed, developed and tested a community-based model of care to help and support people with SCI after discharge.It primarily involved telephone-based advice and support supplemented with a few home visits which can be easily provided in a LMIC like Bangladesh. My hypothesis was that this community-based model of care could help people with SCI to prevent and manage their complications after discharge from hospital. This model of care may be a more viable alternative than other models of community-based support post-discharge in Bangladesh where health care services are insufficient and it is often difficult for people to access specialised care. However, no study has investigated the effectiveness of this model of care. Similarly, no study has looked at survival post-discharge. I sought to address these knowledge gaps in my thesis.

My thesis includes a cohort study designed to determine five-year survival in people with SCI in Bangladesh following discharge from hospital and to develop a prediction model for those at high risk of death. The cohort study also looked at the health status and quality of life (QoL) of these people six years after discharge. My thesis also includes a randomised controlled trialcalled the CIVIC trial,designed to determine the effectiveness of a low-cost community-based intervention to support people with SCI who were recently discharged from hospital in Bangladesh. The acronym CIVIC was derived from the title of the trial, namey –Community-based InterVentions to prevent serIous Complications following spinal cord injury in Bangladesh.Three protocols were developed as a part of the CIVIC trial; these are (i) a protocol for the CIVIC trial,(ii) a protocol for the process evaluation of the CIVIC trial, and (iii) a Statistical Analysis Plan (SAP) for the CIVIC trial.The protocol for the CIVIC trial was developed prior to my doctoral degree, and the latter two protocolswere developed as a part of my doctoral degree. Moreover, a cross-sectional study was conducted from the baseline data of the CIVIC trial to determine the level of impoverishment following SCI in Bangladesh. The summary of the cohort study and CIVIC trialare provided in the next section. Both studies had multiple publications associated with them.

THE COHORT STUDY

Study one: This study investigated thefive-year survival after discharge from hospital in Bangladesh. As part of this study I also developed a prediction model to identify people at risk of death following hospital discharge.Three hundred and forty-five people with SCI who were admitted and survived to discharge in 2011 were followed up in this study. Three hundred and forty-twopeople were accounted for at five years. Seventy-four participants

(22%) had died (survival = 78%; 95% Confidence Interval [CI] 74–82%). Sixty nine of the 223 participants who were wheelchair-dependent at discharge had died (survival = 69%; 95% CI, 62–75%).

A simplemodel predicted survival as a function of age and mode of mobility at discharge (wheelchair-dependent or ambulant). The model showsthat the odds of dying increased by a factor of 1.6 (95% CI, 1.3 to 2.0) with every decade of age and by a factor of 12.6 (95% CI, 4.8 to 32.9) if wheelchair-dependent. This model could help clinicians to identify people with SCI who are at high risk of death following dischargealthough themodel is yet tobe externally validated.

Study two: This study followed up 260 people with SCI six years after discharge from a hospital in Bangladesh. This study looked at health status, QoL and socioeconomic situation. The findings from this study suggest:(i)14%of the cohort and 23% of those who used wheelchairs had pressure ulcers at the time of interview, (ii) the QoLscores as captured on the SF 12 indicated there were more problems in the physical health domain (median 44; interquartile range [IQR]40 to 51) than the mental health domain (median 54, IQR 49 to 57), (iii)there were low levels of depression among the participants who survived until six years; median (IQR) Centre for Epidemiologic Studies DepressionScalerevised version (CESD-R) total scores of 7 (4 to 13), (iv)therewere some problems in participation in society reflected in a median (IQR) World Health Organisation Disability Assessment Schedule version two (WHODAS 2.0)score of 12 (6 to 17), and many participants were unemployed (44%).This study provided a clear picture of the health status, QoL and financial situation of people with SCI six years after discharge from hospital in Bangladesh.

THE CIVIC TRIAL

Study three: This was the statistical plan for the CIVIC trial. This planoutlined the primary effectiveness analysis: a between-group comparison of the hazard of death by any cause. The statistical plan helped guide the statistical analysis of the CIVIC trial and alsominimised the potential for bias and data manipulation.

Study four: This study outlined the protocol for the process evaluation of the CIVIC trial. This study explained the theoretical framework recommended by the Medical Research Council's guidance on process evaluations of complex interventions. It also outlined use of the Realist and Reach, Effectiveness, Adoption, Implementation and Maintenance frameworks. This study provided the details on how the process evaluation data of the CIVIC trial wouldbe analysed to explain the results. It also summarised how I planned to use the data to determine the feasibility of scaling up the intervention in LMICs if the intervention was found to be effective.

Study five: This study was conducted usingthe baseline data fromthe CIVIC trial. Four hundred and ten wheelchair-dependent people with recent SCI about to be discharged from a hospital in Bangladesh were interviewed to determine the size of their families, their incomes from paid work prior to injury and the incomes of their family members.This study showed 74% of participants were the main income earners for their combined families. The median (IQR) family size was 5 (4 to 6) people.Prior to injury, participants' median (IQR) monthly income was $US 106 ($US 60 to $US 180) per person and family members' income was $US 30 ($US 19 to $US 48) per person. After injury and with the loss of the injured person's income, the median (IQR) income of each family member dropped to $US 0 ($US 0

to $US 18) placing 91% of families below the extreme poverty line of $US 37.50 per person per month (equivalent to $US 1.25 per day). This study suggests that SCI leads to severe impoverishment. The impoverishment does not affect only the people with SCI, but it also affects their families.

Study six: This study investigated the overall process and delivery of the intervention of the CIVIC trial. It determined how the intervention of the CIVIC trial was delivered and perceived by the participants and healthcare professionalsof the CIVIC trial. This study suggests that the intervention of the CIVIC trial was delivered as intended and, the participants and healthcare professionalsvalued the intervention. This study also found that people with SCI in Bangladesh face many problems that affect their lives after SCI. These problems may be too big to be addressed by the CIVIC intervention, which may explain the failure of the CIVIC trial toprevent premature deaths.

Study seven: This study presents the results of the main effectiveness analysisof the CIVIC trial. The aim of the trial was to determine whether my community-based model of care reduces premature mortality and prevents serious complications for 410 people with recent SCI in Bangladesh.The primary outcome was all-cause mortality at two years post-discharge. The secondary outcomes were burden of complications, prevalence and severity of pressure ulcers, depression, QoL, independence and participation. The incidence of death was nearly identical in both groups (control and experimental). At twoyears post-discharge 15/204 (7·4%) of 204 participants in the intervention group and 16/206 (7·8%) of participants in the control group had died. The unadjusted hazard ratio was 0·93 (95% CI, 0·46 to 1·89; p value from the log rank test 0·85). None of the sensitivity analyses

demonstrated clinically important or statistically significant effects on survival. This result indicates that my community-based mode of caredoes not add additional benefits compared to usual care and it does not reduce mortality for people with SCI who were discharged from hospital in Bangladesh.

Implications of these studies

Five-year survival and QoLfollowing SCI in Bangladesh arepoor and people with SCI face many obstacles including poverty after discharge from hospital.The prediction model developed in my firststudywill help clinicians identify people with SCI who are at high risk of death after discharge.In this way, clinicians can prioritise services to those most at risk of dying following discharge.

The community-based intervention tested in the CIVIC trial did not reduce mortality and did not prevent complications for peopleSCI following discharge. These results are important for health service providers and policy makers, particularly those in LMICs because they can use the results to prioritise care and services. However, the results need to be interpreted with caution because there may be other benefits from the intervention which were not captured in the trial. In addition, further research is required to determine whether different types of people benefit from the intervention. For example, perhaps those discharged without completingcomprehensive rehabilitation in Bangladesh would derive more benefit from the intervention than those studies in the CIVIC trial. In these patients, the intervention may reducemortality after discharge.This hypothesis is yet to be tested.

Acknowledgments

The CIVIC trial was a big undertaking and required the collaboration and support of many different people and organisations. They were all immensely important to ensuring its success. I would like to acknowledge them all.

I want to express my deepest gratitude to my supervisor,**Professor Lisa Harvey,**who has given herendless time and support to the CIVIC trial. I have been constantly motivated to work for my PhD under her guidance, motivation and encouragement. Her contributions to my studies are remarkable and I humbly recognise her for this. Her enthusiasm in supervising me along with other students is really impressive because she is extremely patient and carefully took her time to explain any topics I asked about even though it was repetitive. I have deeper respect for her because, over and above her continuous support for the CIVIC trial,she also has given me huge support to improve my writing skills in English. This support was very important for me being a student of a country where English is my second language. I thank also my auxiliary supervisor, Professor Rob Herbert, who was very keen and guided me along the way, and for his regular teaching on rigorous research methodology. Moreover, I acknowledge the contributions of my two other auxiliary supervisors (Professor Ian Cameron and Dr Hueiming Liu) for their valuable support and guidance to my studies.

Similarly, I would like to recognise the input of staff who worked on the CIVIC Trial at the Centre for the Rehabilitation of the Paralysed (CRP), Bangladesh and other staff members of CRP who were very cooperativefrom the beginning to the end ofthe trial. In addition, my

appreciation and thanks to the valuable participants of my studies: people with SCI inBangladesh. Without their voluntary participation my studies could not have beencompleted. I wish them all happiness and success in their lives. They have many challenges to face living with a SCI in Bangladesh, and they are all an inspiration to everyone in their own ways.

Importantly,I wish to acknowledge and thank my family for their enormous devotionand patience during my study abroad. Without their support I would not have had the peace of mind to continue my study for such a long time away from them. They are my wife: Sufia Nurjahan, my daughters: Fatema Jannat and Fariha Tabassum, and my son: Jubair Hossain.

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Preface

This thesis consists of two main bodies of work: a Cohort Study and the CIVIC Trial. It is divided into 4 sections and 10 chapters. The 4 sections include: (i) Introduction, (ii) the cohort study, (iii) the CIVIC trial and (iv) the Discussion and Conclusions. Chapters 3, 4, 5, 6, 7, 8 and 9 contain the seven papers which have been published in peer-reviewed journals. The papers are presented in the format that they were published or submitted for publication and include:

Chapter 3: Mohammad Sohrab Hossain, Lisa A. Harvey, Md. Shofiqul Islam, Md. Akhlasur Rahman, Joanne V. Glinsky, Robert D. Herbert. A prediction model to identify people with spinal cord injury whoare at high risk of dying within five years of discharge from hospital inBangladesh. Spinal Cord (2019) 57:198–205.

Chapter 4: Mohammad Sohrab Hossain, Md. Shofiqul Islam, Md. Akhlasur Rahman, Joanne V. Glinsky, Robert D. Herbert, Stanley Ducharme, Lisa A. Harvey. Health status, quality of life and socioeconomic situation of peoplewith spinal cord injuries six years after discharge from a hospitalin Bangladesh. Spinal Cord (2019) 57:652–661.

Chapter 5: Robert D. Herbert, Lisa A Harvey, Mohammad S. Hossain, Md. Shofiqul Islam, Qiang Li, Laurent BillotandThe CIVIC Trial Collaboration. Community-based interventions to preventserious complications following spinal cordinjury in Bangladesh: the CIVIC trial statisticalanalysis plan. BMC Trials (2019) 20:238.

Chapter 6: Mohammad Sohrab Hossain, Lisa A Harvey, Hueiming Liu, Md. Shofiqul Islam, Md. Akhlasur Rahman, Stephen Muldoon, Fin Biering-Sorensen, Ian D Cameron, Harvinder S Chhabra, Richard I Lindley, Stephen Jan. Protocol for process evaluation of CIVIC randomised controlled trial: Community-based interventions to prevent serious complications following spinal cordinjury in Bangladesh. BMJ Open (2018);8: e024226. doi:10.1136/bmjopen-2018-024226.

Chapter 7: Mohammad Sohrab Hossain, Lisa A. Harvey, Md. Shofiqul Islam, Md. Akhlasur Rahman, Hueiming Liu, Robert D. Herberton behalf of the CIVIC Trial Collaboration.Loss of work-related income impoverishes people with spinal cord injury and theirfamilies in Bangladesh. Spinal Cord (2020) 58:423–429.

Chapter 8: Hueiming Liu, Mohammad Sohrab Hossain, Md. Shofiqul Islam, Md. Akhlasur Rahman, Punam D Costa, Robert D Herbert, Stephen Jan, Ian D Cameron, Stephen Muldoon, Harvinder Singh Chhabra, Richard Lindley, Fin Biering-Sorensen, Stanley Ducharme, Valerie Taylor, Lisa A Harvey. Understanding how a community-based intervention for people with spinal cord injury in Bangladesh was delivered as part of a randomised controlled trial: a process evaluation. Spinal Cord (2020). Doi: 10.1038/s41393-020-0495-6.

Chapter 9: Mohammad Sohrab Hossain, Lisa A Harvey, Md. Shofiqul Islam, Md. Akhlasur Rahman, Stephen Muldoon, Fin Biering-Sorensen, Stephen Jan, Hueiming Liu, Qiang Li, Ian D Cameron, Valerie Taylor, Richard I Lindley, Laurent Billot, Robert D Herbert. Community-based interventions to prevent serious complications and premature death after spinal cord

injury in Bangladesh (CIVIC): a randomised controlled trial. Accepted for publication on 12th Aug 2020, Spinal Cord.

SECTION 1: INTRODUCTION and BACKGROUND

Chapter 1 Introduction

1.1 Background and research problem

Spinal cord injury (SCI) has severe physical, psychological and social implications [1]. The most obvious implication is paralysis and loss of mobility. However, people with SCI also suffer many secondary complications. The most common complicationsinclude pressure ulcers, respiratory and urinary tract infections, depression, urinary incontinence and autonomic dysreflexia[2, 3].People who sustain SCI in low-and middle-income countries (LMICs) are especially vulnerable to these types of problems and particularly in the period immediately after discharge from hospital. These complications can be life-threatening and can cause premature death [3-5].

One review study indicates that the incidence of SCI is between 10 and 83 per million [6] but other studies provide different estimates which range from 6 to 246 per million[7-12]. For example, some studies suggest that the incidence of SCI in United States (US), Europe and Asia are respectively 17 to 83, 3.3 to 130.6, and 6.7 to 246 cases per million per year[13]. The prevalence of SCI (i.e. the number of people living with SCI in one time)is more difficult to ascertain but estimates suggest that it is between 50 to 1300 cases per million in high-income countries (HICs) [13]. With 60% of the world's population living in low- and middle -income countries (LMICs)and with such high rates of SCI, we can only estimate that the number of people living with a SCI in LMICs at any one time is substantially higher than HICs[14] even after taking into account the high mortality rates.

Most people who sustain a SCI in Bangladesh are young men. They come from poor socioeconomic backgrounds and suffer muchhardship and secondary complications. Spinal cord injury in Bangladesh does not affect only the person injured but also the families of those affected because in most situations the main income earner is injured[15]. We do not know accurately what the socioeconomic situation and secondary health conditions are following SCI in Bangladesh, but anecdotal evidence suggests that they are profound.

People with SCI in Bangladesh have limited access to appropriate healthcare services and community support. There are only two hospitals in Bangladesh which provide treatment and rehabilitation for people with SCI. However, these services are inadequate for a country like Bangladesh with a population of 161.4 million. For some people, the closest hospital with SCI services is approximately a 10 to 18-hour bumpy-road trip away from their homes.In addition, many people with SCI are very poor and cannot afford treatment. There are local government hospitals to provide services for people in Bangladesh but these hospitalscannot cater for people with SCI. They largely lack staff with the appropriate knowledge and skills, and they do not have facilities for treatment and rehabilitation for people with SCI. Consequently, many people with SCI do not receive any treatment. Even those who do get to hospital and receive rehabilitation still face many hurdles when discharged home. For example, people with SCI do not often go out of their homes. This is because the surroundings in Bangladeshare not wheelchair friendly. As a result, people with SCIhave very limited ability to participate in community and social events [1]. This leads to social isolation and can contribute to depression[16].

People with SCIlive with many complications after being discharged from hospital. The common complications are pressure ulcers, respiratory tract infections, urinary tract infections, contractures and pain[17-20]. These complications can be life threatening and consequently lead to premature death.They are particularly common in LMICs although there is little high-quality evidence to indicate the scale of the problem. The few available studies rely on small samples of convenience thus the results may not be a true reflection of people withSCI living in LMICs [21-26].These studies however all suggest that the health status of people with SCI living in LMICs is poor and they suffer many problems after discharge from hospital.

The high incidence of complications following discharge leads to high rates of premature death. The World Health Organisation declared that the risk of premature death is two to five times higher for people with SCI compared to those without a SCI in LMICs [27]. One of our previous studies found 20% of people who sustained a SCI and were wheelchair-dependent died within two years of hospital discharge [11]. Of the other available information, mortality rates are highly variable across different countries. One systematic review indicated that the rate of mortalityfrom one to five years following SCI may vary from 1% to 32%. This systematic review also highlighted that the rate of mortality is three times higher in LMICs compared to HICs [4]. The varying rates of premature mortality following SCI may primarily reflect availability of care and contextual factors. However, at least some of these differences probably reflect the varying and often poor methodology of the available studies. Nonetheless, premature death following SCI in LMICs is clearly a major problem.

Despite the problems of premature death following SCI in LIMCs, we have very little evidence about appropriate strategies or interventions to prevent these.For example, there are no randomised controlled trials (RCTs) looking at the effectiveness of any community-based intervention designed to support people with SCI living in LMICs and reduce premature death. The exception is one RCTthat examined the effectiveness of telephone-based management of pressure ulcers in people with SCI living in Bangladesh and India [28]. The primary outcome of that RCT was size of pressure ulcers at 12 weeks (death was not an outcome measure). The results of the study were inconclusive. That is, it was not clear whether people with SCI can be supported at home to manage their pressure ulcers through regular telephone-based advice and support. Nonetheless, this RCT stated that there was some indication that a simple telephone-based intervention may benefit people with SCI in respect to their general health and participation. Parts of the intervention of this study guided the development of the intervention that I went on to develop as part of my PhD research.

1.2 Research aims

My PhD research was directed at trying to better understand the high mortality rates following discharge from hospital with SCI in LMICs, and how best to tackle this issue. One of the primary aims was to obtain accurate estimates of survival and mortality five years after discharge from hospital. Mortality following discharge from hospitalis highly dependent on health status and secondary complications of people with SCI. Hence, another aim was to investigate the health status and QoL of those who survive five years following SCI. A major part of my thesis was devoted to designing and testingthe effectiveness of a low costcommunity-based intervention to prevent serious complications and premature death

after SCI in Bangladesh on a large and representative sample of people with SCI in Bangladesh.Two large studies were conducted to achieve my aims:

- A five-year follow-up cohort study
- A clinical trial namely the CIVIC trial.

These two studies consist of the following 7 sub studies with different aims as outlined below.

THE COHORT STUDY

Study one

Title:A prediction model to identify people with SCI likely to die within five years of discharge from hospital in Bangladesh: amixed retrospective and prospective longitudinal cohort study.

Aim:To determine five-year survival after hospitalisation with SCI in Bangladesh, and to develop a prediction model to identify people at risk of death following hospital discharge.

Study two

Title:Health status, quality of life and socioeconomic situation of people with spinal cord injuries six years after discharge from a hospital in Bangladesh: a mixed retrospective and prospective longitudinal study.

Aim: To determine health status, QoL and socioeconomic situation of people with spinal cord injuries sixyears after discharge from a hospital in Bangladesh.

THE CIVIC TRIAL

Study three

Title: Community-based interventions to prevent serious complications following spinal cord injury in Bangladesh: The CIVIC trial statistical analysis plan.

Aim: To develop a protocol for the statisticalanalysis of the CIVIC trial.

Study four

Title: Protocol for process evaluation of the CIVIC randomised controlled trial.

Aim: To develop a protocol for the process evaluation of the CIVIC trial.

Study five

Title: Loss of work-related income impoverishes people with spinal cord injury and their families in Bangladesh.

Aim: To determine the degree of impoverishment of people with SCI and their families in Bangladesh caused by loss of work-related income following injury.

Study six

Title: Understanding how a community-based intervention for people with spinal cord injury in Bangladesh was delivered as part of the CIVIC trial: a process evaluation

Aim: To understand how a community-based intervention for people with SCI in Bangladesh was delivered as part of a randomised controlled trial and to gauge the perceptions of participants and healthcare professionals to the intervention.

Study seven

Title: Community-based interventions to prevent serious complications (CIVIC) following spinal cord injury in Bangladesh: arandomised controlled trial.

Aim: To investigate a sustainable low-cost community-based intervention to prevent serious complications following SCI in Bangladesh: A randomised controlled trial.

Chapter 2 Literature Review

2.1 Bangladesh

The focus of this thesis is Bangladesh. Bangladeshbecame independent in 1971 from West Pakistan. Itis a country with an estimated population of 164 million. The country is progressing from a low-income country to middle-income country, but access to high-quality health services remains underdeveloped. Current life expectancy is 71 years. However, injuries and non-communicable diseases remain amassive health challenge. Accidents and injuries cause many deaths and result in even more disabilities. Spinal cord injuries (SCI) are very common in Bangladesh but there is a lack of emergency and post hospitalisation care. There are inadequate essential emergency rescue services, rehabilitation services, counselling services and preventative services for people with SCI in Bangladesh. There isalso a lack of skilled health professionals to deliver rehabilitation services for people with SCI. Therefore, people with SCI are mostly deprived from essential care. A similar situation is observed in neighbour countries [29] and other LMICs.Therefore, much of what is written about this in my thesis is relevant to most LMICs although I have specifically focused on Bangladesh; my country of birth and the country in which I work.

2.2 Overview of spinal cord injury

Spinal cord injuries (SCI) are the result of trauma or spinaldiseases, and result in either tetraplegia (loss of function below the neck) or paraplegia (loss of function below the chest). The extent of injury is categorised according to the International Standard for Neurological Classification of SCI [30-33]. Spinal cord injuries are classified as either complete or incomplete according to the American Spinal Injury Association (ASIA) Impairment Scale

(AIS).The American Spinal Injury Association Impairment Scale defines a complete injury (AIS A)as: no motor or sensory function in the sacral segment S4-S5. It defines an incomplete injury (AIS B, C, D or E)as: some motor or sensory function in the sacral segment S4-S5. The distinction between different types of incomplete lesions is determined by the extent of motor and sensory sparing [33].

Spinal cord injury is associated with lifetime complications. These include pressure ulcers, pain, contractures, respiratory problems, as well as bowel and bladder dysfunction[17, 20]. In addition, SCI affects the psychological status of the injured person[1, 34, 35]. Notably, people with SCI in LMICs struggle to survive following discharge due to these and other secondary complications[2, 5]. Many die prematurely and those who survive live with hardship and life-threatening complications such as pressure ulcers[11, 26, 36].

2.3 Common types of spinal cord injuries in low- and middle-income countries

In HICs there has been an increase in the ratio of incomplete injuries compared to complete injuries. However, this pattern does not seem to be evident in LMICs where complete injuries seem to be more common than incomplete injuries. For example, studies conducted in Bangladesh reported that, approximately 90% of people with SCI admitted to hospital had complete paralysisand were unable to walk[24, 25]. Of course, this may merely reflect the types of patients admitted to specialised SCI centres in LMICs from where most data originate. These centres may be more likely to admit those with more severe injuries. Nonetheless, anecdotal evidence also suggests that the injuries tend to be more severe and complete in LMICs than HICs. One explanation for this is the lack of awareness about SCI in the community. Consequently, people are often moved or inappropriately transported to

hospital in the hours immediately after injury,causing potentially incomplete injuriesto becomecomplete injuries [3, 29, 37].

In LMICs, as in HICs, males are more likely to sustain a SCI than females. However, the ratio of males to females is approximately 7:1 rather than the 4:1 as seen in HICs [6, 10, 38]. Most injured are young with at least 70% being under the age of 40 years[24-26, 39]. Young males are overrepresented because they are exposed to injuries from their work outside their homes (as discussed below) whereas women are more involved in household activities [6, 25].Mostinjured people have large numbers of dependants and families to support.

2.4 Causes of spinal cord injury in Bangladesh

The causes and mechanism of injuries in Bangladesh are comparable to other LMICs [6, 38]. For example, in Bangladesh most SCI are due to work-related trauma such as low falls, falls from heights and road traffic accidents [24]. There are two common types of falls. The first is falling whilst climbing mango trees during the mango picking season. People climb trees to harvest mangoes but they do not wear safety equipment/gear thus they fall and sustain SCI. The second cause of falls is due to carrying heavy loads on the head. The farmers and labourers carry heavy loads on their heads in order to transport agricultural products including fruits and vegetables from their farms to vehicles or between vehicles. These people often fall while carrying the loads on their heads and sustain cervical spine injuries [39]. Another emerging cause of SCI in Bangladesh is scarf strangulation. This occurs in young school age girls wearing traditional dress whilst travelling on three-wheeled motor vehicles. The scarves get caught in the motor causing a strangulation injury[40, 41].

2.5 Incidence of spinal cord injury

There arefew reliable incidence data about SCI globally, but from the available information it appears that the incidence of SCI varies from country to country. One review study identified 1123 studies from 1995 onwards and reportedan incidence of SCI of between 10 and 83 per million (equivalent to 77,000 to 639,100 globally) [6]. This study stated the incidence of SCI has increased in some parts of the world over the last 30 years. However, the source data were notadequately rigorous to accurately estimate the incidence of SCI. Nonetheless the estimates provided in this paper are widely cited (610 cites).

Similarly, another study reviewed current literature from 1959 until 2011 to find the incidence of traumatic SCI in different parts of the world. The results of this review showed that the global incidence rate in 2007 was estimated at 23 traumatic SCI cases per million per year [9]. This study described the proportion of traumatic injuries increasing in LMICs compared to HICs due to trends in transport mode, poor infrastructure and regulatory challenges. This study also identified a common cause of SCI aslow fallswhile carrying heavy loads on head. Yet the World Health Organisation (WHO) puts the estimate much higher: at 32 to 66 per million (equivalent to 250,000 to 500,000 people per year worldwide) [3]. The incidence of SCI in LMICs is probably even higher with estimates varying from 14 to 80 cases per million per year [10]. There are two studies from Bangladesh but neither provides accurate estimates. One shows that SCI occurs most commonly in the age group of 20-40 years and men are seven times more likely to sustain an injurythan women [25]. The other reported that people living in the rural areas are twice as likely to have a SCI than those living in urban areas [42]. Like these studies, most estimates from LMICs are not reliable because studies have not been conducted on populations. Consequently, we do not know

have accurate estimates ofthe incidence of SCI in LMICs such as Bangladesh but we assume from our observations and anecdotal evidence that SCI are very common [24].

2.6 Treatment and rehabilitation following spinal cord injury in Bangladesh

People in Bangladesh who sustain SCI require extensive treatment and rehabilitation to reintegrate them into the community. However, there is a shortage of rehabilitation services for people with SCI in Bangladesh. Rehabilitation services are only provided at two tertiary level hospitals. These are the Centre for the Rehabilitation of the Paralysed (CRP) and National Institute of Traumatology and Orthopaedic Rehabilitation. Both hospitals are located in Dhaka, the capital of Bangladesh.

The CRP is the only non-government hospital of its kind. It provides comprehensive rehabilitation and reintegration for people with SCI in Bangladesh.This hospital is the largest SCI rehabilitation hospital in the country and even in the region. This hospital's main rehabilitation services are located at Savar which is 29 kilometres from Dhaka. It delivers treatment and rehabilitation with the costs subsidised for people with SCI and other disabilities [39]. The CRPreceives funding from government, national and international donors to support financially disadvantaged people with SCI.

The government hospitals in Bangladesh deliver health services in three sectors: primary, secondary and tertiary hospitals. The tertiary hospitals and/or specialised hospitals usually offer services for people with severe diseases and illness. However, there is no SCI rehabilitation government hospital to offer treatment, rehabilitation and reintegration for people with SCI in Bangladesh except theNational Institute of Traumatology and

Orthopaedic Rehabilitation. There is limited bed capacity for people with SCI at the National Institute of Traumatology and Orthopaedic Rehabilitation.

Many people with SCI do not go to either CRP or the National Institute of Traumatology and Orthopaedic Rehabilitation for treatment.Instead they go to other government or private hospitals in Bangladesh. However, they do not receive rehabilitation services because these services are not available in these hospitals. In addition, they are required to pay for their own care because there is no financial support from the government or from the private insurers. This creates a very big financial strain on families because most people who sustain a SCI come from poor socioeconomic backgrounds.

The limited bed availability for people with SCI in Bangladesh means that many people with SCI do not receive any treatment or rehabilitation and are often discharged home after a few days of hospital admission. Some never even get to hospital because of lack of money. Those that do receive inpatient care and rehabilitation, rarely get support after discharge from hospital.The cost of medical care and rehabilitation also places a large economic burden on individuals and families, and often precludes treatment. Those who survive to discharge often go on to develop life-threatening complications for which they cannot access or afford treatment [43].

Mobility in Bangladesh for those with SCI is very problematic because the environment is very inaccessible. People require extensive mobility aids and assistive devices such as wheelchairs to get about. In addition, they require training in the use of these aids and devices. This is a vital part of rehabilitation. Consequently, a lot of people with SCI remain

homebound, isolated and very dependent on caregiver support for their activities of daily living. This adversely affects their QoL and places a lot of burden and responsibility on families.

2.7 Survivalfollowing spinal cord injury in high-income countries andlow-and middle-income countries

Survival following SCI variesworldwide. A systematic review was conducted to determine survival following traumatic SCI. It identified78 eligible studies. A meta-analysis was performed using the data from 63 studies.However, only 38 of the 63 studies included a large representative sampleof people with SCI. The meta-analyses found an overall in-hospital mortality rate following traumatic SCI for all countries of the world (including countries from Africa, America, Europe and Western Pacific) of 8.0% (95% CI, 6.6 to 9.6) but it varied by up to 24% for different HICs. The review concluded that the in-hospital mortality rates in LMICs were nearly three times higher than those for HICs.This review also looked at overall one-year survival rate. It was 93% (95% CI, 89.4 to 95.2) in HICs [4].

Another systematic review of articles published between 1997 and 2009 reported on survival after traumatic and non-traumatic SCI. There was heterogeneity in the identified papers in relation to methodology and outcomes, therefore a meta-analysis was not performed. Fifty-eight publications were retrieved and evaluated but only 16 provided survival data. This review concluded that survival following SCI at one year and five years post injuryranged from 84% to 99%, and 69% to 99%, respectively [44].

Most studies agree that survival is lower in LMICs compared to HICs [11, 45-50].One study suggests that the rate of survival in the early years following SCI in LMIC is one third that of HICs[4]. Most of the premature deaths occur soon after injury or within the first two years of discharge from hospital [26, 51, 52]. In Bangladesh, people with SCI die soon after injury before they even reach hospital. They also die before and after discharge. Even those who receive extensive treatment and rehabilitation are vulnerable to dying soon after discharge. We conducted a cohort study to determine mortality rates two years post-discharge in a cohort of people with recent SCI discharged from CRP, Bangladesh in 2011 [11]. This study included a consecutive series of 350 people who sustained SCI in the preceding year. We found that 20% of people with SCI who were wheelchair-dependent at the time of discharge had died within two years of discharge from hospital. Those who died suffered many complications including pressure ulcersand, bowel and bladder problems. The poor survival following discharge in LMICs like Bangladesh in is part due to the limited access to health services and emergency care [3], and the limited skills and education of health professionals in the management of people with SCI [50]. Of course, survival followingdischarge is also influenced by many other factors including access to appropriate equipment and devices (which are discussed in more depth later in this chapter).

Thereare little other data about survival after discharge for people with SCI in LMICs apart from a few studies that have looked at survival after injury from samples of convenience[26, 45, 53].One notable study is from a tertiary rehabilitation hospital in southern India. The authors of this study attempted to determine the survival rate post-discharge. The researchers retrospectively collected data from chart audits between 1981 and 2011. More than 2,000 people were admitted with a SCI over the time period, but the authors only

looked at those whosurvived to discharge, lived within a 100 kilometre radius of the hospital and had received regular follow-up at the hospital. This equated to 537 people. Of these 537 people, 490 were included in this studywith 47 participants lost to follow-up. The study reported an 86% survival rate at five years after discharge. However, this estimate is likely to be a poor reflection of survival because those most likely to have died post-discharge probably did not receive regular follow-up. Hence the 537 people may only reflect a small proportion of those wholived within 100 kilometres of the hospital. This problem is particularly evident for the period from 1981to 1991 where there was a disproportionally small number of participants compared to after 1991[54]. Other than this study from India and our own from Bangladesh, there are very little survival data post-dischargefrom LMICs. In most LMICs we do not even know how many people sustain a SCI and how many of these are then admitted to hospital.

2.8 Pressure ulcers following spinal cord injury

Pressure ulcers are the leading cause of deathpost-discharge in people with SCI in LMICs [11]. However, some also die from respiratory problems, and bowel and bladder complications [5, 55-57]. Of course, pressure ulcersand other secondary complications also cause premature death following discharge in HICs but this is far less common than in LMICs [58]. In HICs, the most common cause of death post-discharge is cardiovascular disease which usually starts to have its impact some 20 or 30 years post injury [47, 59].Pressure ulcers and other secondary complicationsare not onlylife-threatening but they also adversely affect health and QoL [54, 55]. For example, people with SCI, irrespective of country, often experience difficulties with incontinence, spasticity, pain and musculoskeletal disorders [57]. We found the same in our study [36].

2.8.1 What are pressure ulcers?

Pressure ulcers are wounds due to a lack of adequate blood flow to the skin and underlying tissue. This causes ischemia. The wounds can become infected leading to septicaemia and death. Pressure ulcerstypically develop on the bony prominences of the body which are in contact with hard surfaces such as a bed or chair. The most vulnerable sites are the areas around the sacro-coccyx, greater trochanter and ischium. Pressure ulcers typically develop in those with limited mobility that results in prolonged sitting and lying. They may also develop from injuries sustained during transfers due to friction and shearing forces. They are exacerbated by urinary incontinence [60].

2.8.2 Incidence and prevalence of pressure ulcers

Pressure ulcers are very common in people with SCI in both HICs and LMICs [20, 52, 61-64], although it is difficult to get accurate estimates of just how common they are, particularly in LMICs [2]. The difficulty of attaining accurate estimates of the incidence and prevalence of pressure ulcers is partly due to the complexities of conducting these types of studies. Studies on prevalence require a cross-sectional study of a representative sample. In order to measure incidence or time to first pressure ulcers, a longitudinal study is required that regularly follows up participants over time to identify the onset of pressure ulcers from a point of time (eg. time of discharge). These studies are time consuming and costly. A few studies have attempted to look at this issue but most suffer from important methodological flaws [18, 20, 24, 48, 65]. A notable high-quality study from the US included a population-based sample of people with SCI who survived for five years. This study followed up participants after injuries at one-year, three-year and five-year time points. This study

reported that more than 10% of the participants had pressure ulcers at all three follow-ups[66].

My colleagues and I looked at the prevalence of pressure ulcers following discharge in Bangladesh. In this study a representative sample of people discharged from a large rehabilitation hospital in Bangladesh were followed up two years after discharge. It is notable that there was a high follow-up rate which provided us with confidence in our estimates of pressure ulcers. In this study we found that26% of those who were wheelchair-dependent at discharge had pressure ulcers two yearsafterdischarge from hospital[36].

There are few equivalent studies from LMICswith the exception ofone study from Nepal. This study recruited 129 people with chronic SCI (at least one year post-discharge) and found that 26% of participants had pressure ulcers at the time of interview and another 28% had recently experienced pressure ulcers[60]. Another example is a study involving 107 people with SCI whowere admitted to a hospital in Bangladesh [24]. This study found that 43% of patients had at least one pressure ulcer. However, both these studies used samples of convenience and therefore the estimates are unreliable.

A review article recently summarised the results of other relevant studies in an effort toobtain an estimate of the prevalence of pressure ulcers in LMICs. This review summarised studies published in English between 1998 and 2014 [2]. Itfoundthat the prevalence of pressure ulcers is highly variable from study to study and country to country, and may vary from 3% to 57% although it is extremely prevalent for people with SCI living in LMICs. However, the authors of this systematic review paid little attention to the validity of the

included studies. Therefore, their results and interpretation of the included studies are questionable.

Pressure ulcers can develop at any stage after SCI. Studiessuggest thatpressure ulcersarehighly prevalent during the early stages of rehabilitation despite protocols and treatments in place for their prevention [20, 62]. Other studies suggest that pressure ulcersare also prevalent after discharge [60, 64].A studyfocusing on the clinical outcomes of people with SCI after discharge estimated that 48% of people with SCI sustained at least one pressure ulcers within the first two years of their injuries[67]. Another study found that the cumulative incidence of pressure ulcers was 41% during the first year after discharge [5]. Gelis et.al.stated that 15% to 30% of people develop a pressure ulcers after discharge but it was not clear where this estimate came from and what it really meant [63]. My ownclinical observations from Bangladesh indicate that pressure ulcers are a far greater problem post-discharge when patients do not have the same support and care as provided to them whilst inpatients. However, there are no reliable studies from LMICs on incidence of pressure ulcers to support my observation.

2.8.3 Possible causes of pressure ulcers

Various factors can cause pressure ulcers in people with SCI, although poverty and all its implications haveto be a major cause of pressure ulcers for those living in LMICs [2]. A systematic review was performed to find studies from 2007 to 2017 to evaluate any outcomes related to SCI including pressure ulcers [68]. This review found 403 relevant articles and among those 26 were eligible for inclusion in the review. All included articles were from HICsbut some looked specifically at those with limited access to resources in

these countries. The review indicated that people with limited access to resources experienced more pressure ulcers (OR 2.1, 95% CI 1.5-3.0) and had higher rates of premature death (OR 2.1, 95% CI 1.7-2.6) than those with good access to resources. These findings suggest that people with SCI in low resource settings or LMICs are very vulnerable to developing pressure ulcers secondary to the many implications of poverty, however it is not clear from these studies whether poverty is a predictor or cause of pressure ulcers.

A review suggested that the causes of pressure ulcersarepoverty, low education, limited activity levels and malnutritionin both HICs and LMICs although clearly these contributing factorsare more prevalentin LMICs [2]. Another systematic review identified some other causes of pressure ulcers such as socio-demographic status, neurological conditions and behavioural factors. In addition, level of care and the clinical expertise of acute hospitals were also identified ascauses of pressure ulcers[63]. For example, this systematic review found that people with SCI admitted to regional and non-specialised hospitals are more likely to develop pressure ulcers than those admitted to specialised SCI centres. The study highlighted that once patients are discharged from hospitals then behavioural factors play an important causal role. This included behaviours related to relieving pressure and monitoring skin. They also highlighted the causal role played by socio-demographic background and clinical factors. However, most of the studies devoted to determining the causes of pressure ulcers are either case series or studies based on expert opinion. There are a large number of cohort studies but most have serious methodological weaknesses as highlighted by one of the authors of the systematic review [63]. For example, they rely on cross-sectional studies of non-representative samples, and examine “associations”. It is often not clear whether the authors are interested in causation or prediction even though

the methodology of these two types of studies are very different[69]. Authors often try to circumvent this issue by referring to "risk factors"[70]. Further studies with rigorous methodology are required. For example, we need large longitudinal studies that follow people up over long periods of time and regularly assess participants for pressure ulcers. These types of studies need to begin with a causal diagram to articulate the underlying assumptions about all the various possible associations[71].

2.8.4 The cost of managing pressure ulcers and other complications

There is a large variation in the management of pressure ulcers between HICs and LMICs[3]. The treatment and management of pressure ulcers in HICs are often highly organised and rigorous. They include home services and regular community-based care. Patients also usually have access to highly specialised and costly equipment such as pressure-relieving mattresses [72, 73]. Often patients are hospitalised for the management of pressure ulcersafter discharge hencepressure ulcersare the third leading cause of rehospitalisation [74].Not surprisingly therefore costs are extremely high.A study conducted for people with SCI in the US estimated that the costs of rehospitalisation for pressure ulcers after SCI was $US 1.4 billion annually [75]. Similarly, another study highlighted the cost of managing pressure ulcers is high in United Kingdom (UK). The National Health Services invests large amounts of money for managing pressure ulcers in UK. They spend £1.4–2.1 billion per year on pressure ulcers prevention and treatment [76].

The cost of managing pressure ulcers is also captured in studies that have looked at general health costs following discharge. For example, one study from the US involving 115 people with SCI analysed health costsin those who survived the first two years after injury. This was

a population-based sample of people with SCI living in Colorado, US. This study showed $US 22 million was spent on this cohort during the first two years following SCI ($US 0.1 million per person per year). Of this, $US 6.3 million was spent after hospital discharge, $US 2.5 million (39%) was spent on in-home care and $US 2.0 million (32%) was spent on managing secondary medical complications related to skin problems, respiratory problems and neurological problems [77]. Other studies estimated the average lifetime cost of direct care related to SCI ranges from $US 1.5 to $US 4.7 million per person[78] with $US 5,255 being spent annually per person on in-hospital care [79]. It is therefore not surprising that a country like Bangladesh struggles to provide medical care for those with pressure ulcers and other complications following SCI.

It is not clear how much it costs to manage pressure ulcers and other complications in people with SCI in Bangladesh, however, the costs of re-hospitalisation [63] are prohibitive for most. Re-hospitalisation is cost-prohibitive because it is not government funded and hence most people have to pay for it themselves. This is particularly problematic for those who develop pressure ulcersbecause they often require very extended lengths of stay. For example, one study from Bangladesh indicated thatpatientswith pressure ulcers remained in hospital for much longer than other patients who did not have pressure ulcers[25]. Data from a local hospital indicates that one day of hospitalisation for treating complications like pressure ulcers is approximately $US200. This cost is only related to hospital admission and does not include costs associated with the purchase of medicine, equipment or surgery. Nor does it include the cost of care post-discharge. This is not affordable for most. Consequently, people with

pressure ulcers and other complications are rarely admitted to hospital and instead are left to manage at home alone.

2.8.5 The problems of managing pressure ulcers in low- and middle-income countries

The high rates of pressure ulcers and premature death in LMICs are in part due to the lack of access to health services and associated costs [3]. However, they are also due to the lack of appropriate pressure relieving equipment and devices. In addition, they are caused by limited knowledge about SCI amongst health professionals, and limited access to health care and rehabilitation services in the community [50]. For example, a grade III pressure ulcer can require months of hospitalisation. This type of care is not only extremely costly for individuals and their families (as outlined above) but also difficult to access in Bangladesh because there are few hospitals with the appropriate expertise to manage pressure ulcers.

2.8.6 The prevention of pressure ulcers

The difficulties and cost of treatment of pressure ulcersand other complications points to the importance of prevention as outlined in many studies and clinical practice guidelines [51, 80-82]. There is a lot of information about different strategies to prevent pressure ulcers.These include daily checking of the skin for early signs of skin colour changes. People are also encouraged to keep their skin clean and dry, and to regularly lift to relieve pressure [63, 82]. Self-management is a key strategy for the prevention and control of pressure ulcers [80] but this requires a lifetime commitment [82], and it requires education, motivation and support.Most of the strategies advocated for prevention of pressure ulcers are based on clinical expertise and anecdotal evidence [3, 72], and there are in fact very few high-quality

RCTs examining the effectiveness of any of these strategies with most recommendations based on level four evidence [82]. Of course, this primarily reflects the difficulties of conducting RCTs on these issues and does not negate the importance of different and widely acknowledged preventative strategies.

It is widely believed that education is the first step to the prevention of pressure ulcers. This includes education about the use of appropriate bed mattresses and wheeclchair cushions, as well as education about regular change of position and good nutrition [83]. However, it is not education alone because people need to also change their health behaviours. A recent systematic review looked at the outcome of educational interventions to prevent pressure ulcersin community-dwelling adult people with SCI aged 18 years and older [84]. This review identified only three RCTs (two were quasi-experimental designs) related to educational interventions for the prevention ofpressure ulcers for people with SCI. None of the included studies demonstrated an effect on pressure ulcers. However, this probably merely reflects the lack of studies in this area and should not be interpreted that the interventions investigated in these studies were ineffective. Importantly, there were also methodological weaknesses with recruitment, intervention fidelity, and participant adherence in the three studies. Clearly high-quality studies arerequired to better understand the effectiveness of different educational strategies for the prevention of pressure ulcers, and the barriers of adopting them.

The prevention of pressure ulcers is difficult because people with SCI do not always adopt appropriate strategies to prevent pressure ulcers for a whole range of reasons. For example, a farmer with SCI living in rural Bangladesh may be well aware that he needs to sleep on a

well-supported mattress and remain continent. He may also be highly motivated. However, he may fail because of insurmountable problems with continence and lack of access to appropriate mattresses. The challenge is finding ways to encourage and support people with SCI to adopt appropriate strategies and look after themselves within their available resources. Any strategy must be easily accessible in the context of the country.

Prevention of pressure ulcers in a country like Bangladesh is particularly important because once a person develops a pressure ulcer it can quickly become life-threatening.Yet,despite the importance of preventing pressure ulcers, there has been a worldwide failure to effectively operationalise any prevention strategies in Bangladesh or other LMICs.The failure to adequately prevent pressure ulcers in Bangladesh and other LIMCs is in part because any strategy requires money, effort and a life-time commitment. So, prevention is not as simple as it sounds. Nonetheless, the main focus of the CIVIC trial was to test a community-based model of care designed to prevent complications and particularly pressure ulcersin the first two years following discharge, with the ultimate aim of reducing premature mortality.

2.9 Community-based follow-upfor people withspinal cord injuries

This section provides a brief summary about the current practice of community-based follow-up for people with SCI in LMICs.This section is based on aliterature search I conducted to determine what is known of the effectiveness of community-based rehabilitation for people with SCI living in LMICs. The search strategy was based on a search conducted in a Campbell systematic review of community-based follow-up service in LMICs for people with any type of disability or injury[85]. The search was restricted to trials

conducted on people with SCI using the following terms: parapl*, tetrapleg*, spinal cord*, spinal inj*, quadripleg* or paralys*. This was combined with the Cochrane sensitive search strategy for RCTs[86]. A search of Medline, EMBASE and the Cochrane Central Register of Controlled trials using the Ovid platform from inception until 13th April 2020 retrieved 1,317 papers after removal of duplicates. The papers were screened for inclusion based on the following criteria: (a), study conducted in a LMIC, (b), participants had a SCI, (c), the study was aRCT, and (d), the intervention was community-based. Only two studies were identified; both were our own. One was the pilot study for the CIVIC trial [87]and the other was a trial our team conducted in India and Bangladesh to determine the effectiveness of telephone-based support for people with spinal cord injury and pressure ulcers[28]. Details of both studies are reported in more details throughout this section. However, I also searched Scopus, Medline and Google Scholar to explore further evidence related to my cohort and cross-sectional studies.

2.9.1 Different models of community-based care

Community-based follow-up after dischargecan be provided either on an outpatient basis at hospital or in the community [88, 89]. Regardless of how it is provided, it needs to be delivered systematically to be effective [89] and needs to start with a comprehensive assessment.In HICs the model of community-based care for people with SCI post-discharge involves structured follow-up programs. Theseprograms typically involve regular face-to-face follow-up with clinicians [61, 90] in which patients are screened for complications, and provided with advice and support.

There are very fewcommunity-basedfollow-up programmes for people with SCI in Bangladesh and those that do exist are not systematically coordinated. My study focuses on follow-up after discharge provided through telephone calls and occasional home visits. I will refer to this as"*community-based follow-up*". Follow-up provided in this way is more practical than follow-up provided at a hospital because people with SCI in Bangladesh typically need to travel long distances to get to appropriate hospitals. It is therefore too costly and difficult for people with SCI to travel from their homes to hospital. For example, the rehabilitation centres in Savar is between 200 and 500 kilometres away from many patients' homes. This can take 10 to 20 hours of travel because roads and public transportare poor.There are no ambulances for people with SCI to reach hospitals or rehabilitation centres. Moreover, travelling can bepotentially dangerous for those withpressure ulcers. A map is presented below highlighting the distance our participants of the CIVIC trial lived from the main SCI hospital in Savar.

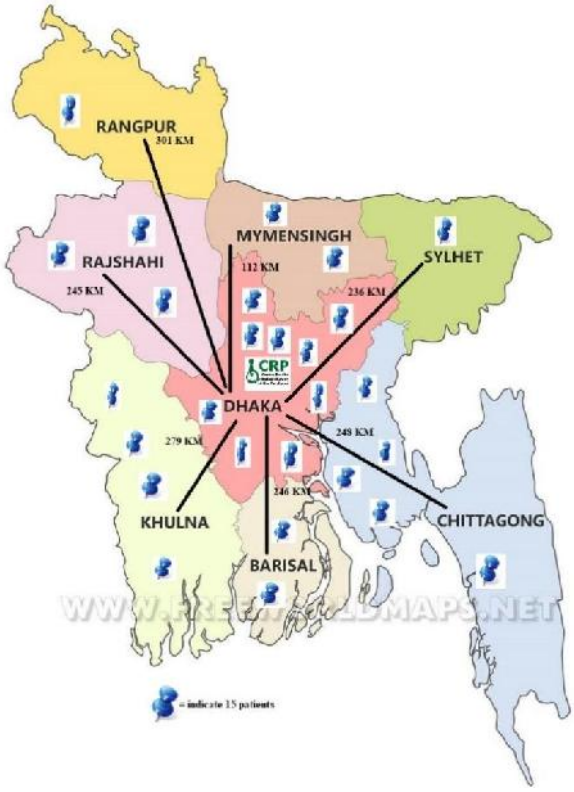

Figure 1: A map highlighting the distance our participants of the CIVIC trial lived from the main hospital in Savar, Dhaka.

2.9.2 The importance of community-based follow-up and care

Community-based follow-upand care is important for supporting people with SCI once they are discharged from hospital andis particularly important for the prevention and management of secondary complications. Community-based follow-up may help people with SCI to manage their secondary complicationsin their homes. It mayalso empower them tomanage their problems independently by improvingtheir knowledge and skills [91]. It can be used to guide people with SCI to appropriate servicesand help them gain employment. Others argue that community-based follow-upultimately improves QoL [92]. Community-based follow-up may also improve independence, mobility and socioeconomic development [93]. However, the outcomes andpossible benefits of community-based interventionshave not yet been tested for people with SCI in Bangladesh and other LMICs.

2.9.3 Telephone-basedfollow-up

This section provides a summary of what we know about the potential benefits and challenges of telephone-based follow-up and support to treat and prevent complications after SCIand other disabilities.

Community-based follow-up and support over the telephone is widely advocated and can be provided cost-effectively and efficiently [89, 94]. It is also appealing as a possible way of helping people with SCI totreat and prevent complications in a country like Bangladesh because so much of prevention and treatment relies on advice, support and close monitoring[28]. Telephone-base support is alsovaluable because it can be provided where frequent face-to-face contact is unattainable due to lack of resources and funding. It is highly feasible to provide telephone-based advice and support ina country like Bangladesh because most people havemobilephones. Mobilephones are cheap and, in addition, Bangladesh has very good telephone coverage. Trained health professionals can easily callpeople with SCI to provide advice and support after discharge from hospitals.

Despite the many advantages and appeal of using the telephone to support people with SCI, the issue is whether telephone-base support is an acceptable alternative toproviding support through face-to-face contact at a person's home. It is possible that face-to-face contact is important for establishing rapport and for motivating people with SCI to adhere to advice. More importantly face-to-face contact may be essential for assessment. There is currently no high-quality evidence to indicate whether telephone-based supportis effective for managing complicationsof people with SCI after discharge. There are however some studies that have tried to tackle similar issues that provide some insights into the possible

effectiveness of telephone-based support for treating and preventing complications following SCI. They are described below.

A study from Canada looked at the effectiveness of a telephone counselling service to increase leisure-time physical activity in people with SCI. A total of 65 people with SCI participated in this study between June 2008 and June 2011. Telephone-based counselling was provided over sixmonths (a total of 14 calls were provided to each participant). Participants were assessed at baseline, two, four and six months. This study found that leisure-time physical activity remained high attwo, four and six monthsand more people were engaged in leisure-time physical activity at six months (52%) than atbaseline (35%). This study concludedthattelephone-based counselling is a promising strategy for improving community-based leisure-time physical activity among people with SCI [89]. However, this was only a pre-post study and therefore the results may be biased. In addition, the possible effectiveness of telephone-based counselling for improving leisure-time physical activity in people with SCI in Canada may have little relevance to our intended uses in Bangladesh.

Another study from Australiareviewed the literature to understand the usefulness of various different types of community-based services for the management of wounds (including pressure ulcers) in people with different type of SCI and non-SCI conditions [95]. As part of this review they examined telephone-based support. This review indicated a large variation inthe way telephone-based support is provided and concluded that as yet there is no strong evidence to indicate thattelephone-based support is effective for helping people to manage their pressure ulcersand other wounds. They also made the point that no evidence is not evidence of no effect.

A few other studies reported substantial complexities and barriers to the provision of telephone-based support [95-97]. These include identifying the types of people with SCIwho would benefit from telephone-based services, and the difficulties of tailoring the support to people'sdiffering levels of understanding and differing disabilities and needs. Nonetheless, they concluded that this this intervention should be prioritised to those who would otherwise have no access totreatment as is the case for most people with SCI in Bangladesh.

A RCT was conducted in the US to examine the effectiveness of telephone-based supportfor reducing medical complications for people with SCI [98]. This RCT compared a telephone counseling service with usual care. It recruited 168people (89% of the eligible participants) from the US SCI model systems database between 2007 to 2010 who met the eligibility criteria and agreed to participate. The treatment group received up to eleven 30- to 45-minute telephone callsover a one-year period in the first year after discharge. The purpose of the telephone calls was to provide health education and support. The primary outcome was health complications. The investigatorsfound no between-group difference on this outcome but did not provide enough data to rule out the possibility of a treatment effect.[] Therefore, it is not clear whether these results indicate that the treatment was ineffective or whether the failure to find a treatment effect merely reflects an insufficient sample size. Nonetheless, the authors concluded that telephone-based support may be promising for

[] The authors only provided the mean and SD of the two groupsin a Supplementary file. However, the data were poorly described and hence it was not clear whether the data were baseline or outcome data. It was therefore not possible to determine a mean between-group difference and corresponding 95% CI.

individuals with SCI because it reduces barriers to care.The authors also hypothesisedthat telephone-based supportmight promote adjustment over the first year following SCI.

Another RCT from the US evaluated the impact of telephone-based supportfor people with SCI living in the community. This study randomised84 people with SCI to either an experimental or control group. The experimental participants (n=42) received 12 telephone calls over a period of 6 months on a tapered call schedule, and the control participants (n = 42) received usual care.The 13-item Patient Activation Measure, which reflects self-management, was the primary outcome. Participants had a greater change in Patient Activation Measure compared to controls at six months, with a mean (95% CI) between-group difference of 7/100 points (0.1 to 14.0). The lower end of the 95% CI indicates a trivially small effect (ie. 0.1 out of 100 points). Nonetheless, the authors claimed that telephone-based support had a positive impact on self-management for the prevention of secondary conditions in adults with SCI.They argued that the telephone-based support promoted self-management and increased participants'ability andwillingnessto take on the dailymanagement of their health care [99].

As indicated at the beginning of this section, I only identified two relevant RCTs from a LMIC. The larger and more important trial was conducted with a group of people with SCI from Bangladesh and India [28]. This RCTattempted to look at the potential benefits of providing advice and support over the telephone for people with SCI and pressure ulcers. The primary outcome (size of pressure ulcers)of this study was inconclusive. Nonetheless, many of the secondary outcomes indicated a beneficial effect. On the basis ofthese results, the study suggested a larger trial to determine the effectiveness of telephone-based support for the

management of pressure ulcers for people with SCI. The other study was our pilot study [87] for the CIVIC trial proper that is discussed in more detail at the end of this chapter.

Onlyone of the studies referred to in this section clearly indicated that telephone-based management of pressure ulcers and other secondary complicationsis effective in people with SCI. Therefore, clinical studies are required to investigate theeffectiveness of this intervention. This was the motivation for the CIVIC trial, the major study of my thesis.

2.9.4 The background to the development of the CIVIC intervention and trial

The intervention for the CIVIC trial was developed over many years. Initially my colleagues and I investigated survival and QoL of people with SCI two years after discharge from hospital [11, 36]. The data from this two-year follow-up studies provided us with essential knowledge about the QoL and survival after SCI in Bangladesh. These findings provided the impetus and motivation to design and test an intervention that might help reduce premature mortality and alleviate suffering. Importantly, the intervention needed to be inexpensive and hence we opted for telephone-based support supplemented with a few home visits provided by trained healthcare professionals. Specifically, the intervention involved 36 telephone calls provided over the first two years following discharge, as well as three home visits. The telephone calls and home visits were designed to educate and monitor participants for any early signs of pressure ulcers and other secondary complications. They were also a means of providing ongoing advice and support to help people prevent and manage their complications.

Initially, we conducted a pilot RCT to determine the feasibility of our proposed intervention and definite trial. This trial included 30 people with recent SCI who were wheelchair-dependent. The pilot study was not designed to determine treatment effectiveness rather it was designed to ensure feasibility. The trial was conducted over two years and run in exactly the same way as my subsequent definitive trial [87]. It provided an invaluable opportunity to train staff, ensure outcomes could be collected, and determine the feasibility of finding people two years post-discharge. The experimental group received our intervention and the control group received usual care provided by CRP. Two participants died (1 control and 1 experimental) and those who survived suffered secondary complications. For example, five participants developed pressure ulcers at two years. The experience and results of this pilot study set us up to secure funding to conduct the definitive clinical trial.

2.10 Outcome measures used in my thesis

This section is devoted to the outcome measures used as part of the CIVIC trial and throughout my thesis. There are a variety of outcome measures that are frequently used in clinical researchto determine outcomes such as burden of complications, prevalence of pressure ulcers, psychosocial status, QoL and independence. They vary in their reliability and validity, and only a few are available in languages like Bangla [100-102]. Someare administered through an interview whilst others are administered through an assessment. Most of the outcomes I used in my studies relied on asking participants'questions about their secondary complications. In this section I summarise the key outcome measures used in my studies. I have used these outcome measures in my studies to attain information about secondary complications and QoL for people with SCI in Bangladesh. My choice of

outcomes measures was restricted by the need to administer them in Bangla (because few people with SCI in Bangladesh speak English).

2.10.1 Spinal Cord Injury Secondary Condition Scale

The burden of secondary complications is usually measured using the SCI Secondary Conditions Scale (SCI-SCS).The SCI-SCS questionnaire measures the following complications: pressure ulcers, respiratory problems, urinary and bladder dysfunction, sexual dysfunction, autonomic dysreflexia, injury caused by loss of sensation, muscle spasm(spasticity), postural hypotension, contractures, heterotopic bone ossification, diabetes mellitus and pain [100, 103].Information regarding participants' experiencesofthese complications in the last three months are captured at the time of interview. The SCI-SCS measurement scale is a validated 16-item questionnairewhich records responses from 0 to 3. A score of zero means that the participant did not suffer any complications in the last three months. In contrast, a score of three means participants suffered significant or chronic problems over the last three months. The score for each item is determined by the interviewersubsequently asking any relevant questions ofthe interviewee if appropriate. The scores aretallied to attain an overall scorefor the SCI-SCS. The total possible score is 48, where the lowest score (0) represents no complications and the highest score (48) represents severe complications.

2.10.2 Pressure Ulcer Scale for Healing

Extent and severity of pressure ulcersarecommonlymeasuredwith the Pressure Ulcer Scale for Healing (PUSH). Skin damage due to injuries and not related to pressure are not

captured in this measurement. For example, skin damage due to cuts or burns are not considered a pressure ulcer.The scores of this measurement capture the size of the pressure ulcers, amount and type of exudate,and level of tissue damage.The size of a pressure ulceris measured in square centimetres with a10-point scale where, '0' represents no pressure ulcerand '10' represents a severe pressure ulcerwith a size greater than 24 square centimetres. A centimetre scale is used to obtain the length and widthof the pressure ulcer. The length and width are multiplied to acquire an estimation of the size of the pressure ulcers. The amount and type of exudatethat exists after removingthe dressing isscored as none('0'), light('1'), moderate('2')orheavy ('3').Similarly, the level of tissue damageisscoredas closed('0'), granulation tissue('1'), epithelial tissue('2'), slough('3')ornecrotic or eschar tissue('4').

2.10.3 Centre for Epidemiologic Studies Depression Scale

The Centre for Epidemiologic Studies Depression (CESD-R) scaleis a measure of depressive symptoms. It is administered through an interview andis not substantially influenced by the normal range of conditions. Importantly, it can be administered in a person's home and does not need to be administered by a psychologist. The validity and reliability are similar across various populations[104, 105]

The CESD-R is reliable when used in people of different ages and from various cultures [105]. The CESD-R scale assesses symptoms of depression experienced by participants over the last week according to the definition of the American Psychiatric Association Diagnostic and Statistical Manual [106-108]. It is a popular outcome measure because the scale is freely available and there are a lot of data for comparing results [104, 109, 110]. This

measure is also appropriate for looking at depressive symptoms in people with different types of physical disabilities and was validated to recognise depression in people with SCI[111].The CESD-Rassesses four factors, these are:affection of depression, absence of positive affect, somatic activity or inactivity, and interpersonalchallenges[105].It was initially not designed to diagnose depression although in more recent years a revised version has been used for this purpose [108].

The original CESD-R contains 20 items and each item is scored on a 4-point scale. The 20 items capture sadness, loss of interest, appetite, sleep, thinking, guilt, tiredness and suicidal ideation. Each of the 20-items of the CESD-R are scored where '0' means 'rarely or none of the time' and '3' means 'most or all of the time'. These questions are self-reported, for example ''I felt hopeful about the future''. Participants use the scale to respond to the questions based on how frequently they experienced each problem over the preceding week. Scores are tallied to a total possible score of 60 where higher scores indicate severe depressive symptoms. Scores for the items 4, 8, 12 and 16 are reversed beforebeing tallied to a total score [105]. The highest score is observed when the personexperiences depressive symptoms across all 20 items on at least five days over the past week.

Peoplewith scores of 16 or more are classified as having subthreshold depressive symptoms, possible depressive disorders, probable depressive disorders or major depressive disorders according to an algorithm. In addition, scores for individual questions are used to determine whether peoplehave symptoms of sadness, loss of interest, appetite, sleep, thinking, guilt, tiredness and suicidal ideation.

2.10.4 Short Form Health Survey

The Short Form Health Survey-12 (SF12) is a self-reported questionnaire use to identify the health-related QoL for people with SCI and other disabilities. The SF12 questionnaire is derived from the physical and mental domains of the SF36. Outcomes are measured using 12 questions which are particularly designed to measure functional health and well-being from theindividuals' perspectives.

Each question of the SF12 survey is scored on a 2- to 6-point scale. The Physical Component Summary and the Mental Component Summary scores are obtain using a standard algorithm. The algorithm system was developed from the final set of 12 questions using data from aUS population-based sample.TheSF12hasa mean of 50 and a standard deviation of 10 in the general U.S. populationTherefore, a score of 30 is equivalent to the lowest 2.5% of the US population. Higher scoresmirror a better QoL.The SF12 has been extensively usedin a number of clinical populations including Bangladesh[112].

2.10.5 Spinal Cord Independence Measure

The Spinal Cord Independence Measure Self Report (SCIM-SR) is commonly used to measureindependence of people with SCI. It consists of 16-items divided into self-care (4 items), respiration and sphincter control (4 items), and mobility (8 items). The items are scored on different scales ranging from 0 to 1 point through to 0 to 15 points. This is done to give weighting to different items. The scores of the SCIM items are tallied to atotal score of 100 points where a higher score reflects more independence, although each item is scored inversely.

2.10.6 World Health Organisation Disability Assessment 2.0

The World Health Organisation Disability Assessment Scale (WHODAS 2.0) is a self-reported questionnaire that is widely used to measure QoL for people with SCI [113-115]. It can be administered for all health conditions, across all cultures, and is valid in both clinical and general populations. This scale is reliable and valid [116]. The WHODAS 2.0 consists of 36 self-reported questions. Eightitems are particularly useful for assessing the participation of people with SCI or other disabilities. Participants are asked to rate each question on a five-point scale (1-5), described as none, mild, moderate, severe or extreme/cannot do. The scores are summed to an overall score. The total possible score in the WHODAS 2.0 participation item is 40. A higher score represents extreme problems with participation.

2.11 Quality of life following spinal cord injury

Quality of life is an important indicator of health and wellbeing, andwas measured in both my studies. This section will therefore provide a brief overview of quality of life following SCI. The outcome of QoL varies depending on what QoL measurement instruments are used and how the outcomes are interpreted. Therefore, care needs to be taken to ensure that people from different countries, cultures and languages clearly understand the questions that are included in QOL assessments [117].

Quality of life is an abstract concept that is perceived differently by people.It is also a multifaceted concept and it includes complex aspects of a person's physical environment, psychological conditions, personality and their social and environmental status. There is a cross-cultural debate among psychologists about whether QoL depends on a specific culture

[118]. Many studies describe QoL as relationships and personal beliefs which may be strongly influenced by cultures[118, 119].“*Quality of life was defined, therefore, as individuals' perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept, incorporating in a complex way individuals' physical health, psychological state, level of independence, social relationships, personal beliefs and their relationships to salient features of the environment*”(pg 1405) [120].

Information about the meaning and components of QoL isvery limited for people with SCI in LMICs. Similarly, there are few studies that have quantified QOLfor people with SCI living in LMICs,particularly in countries like Bangladesh. The few studies that have been conducted in LMICs were conducted in samples of convenience[48, 52, 121, 122]. This includes those studies conducted in Bangladesh [121-123]. For this reason, these studies are exposed to selection biases. Nonetheless, these studies report a poor QoL for people with SCI living in LMICs.

One study conducted in people with SCI in LMICs reported that individuals with SCI living in LMICs perceived much lower QoL than people with SCI in HICs [21, 66, 124]. Unemployment, poor socioeconomic conditions, inaccessible environment and societietal attitudes prevent people with SCI in LMICs achieving a good QoL [21, 125]. On the other hand, a few studies reported that people with severe injuries and disabilities living in the LMICs do not always show the same low levels of QoL as people with equivalent injuries and disabilities living in HICs. This finding may largely be due to cultural, religious and family differences between LMICs and HICs [3, 126, 127].

It is often difficult to ascertain the true picture of QoL for people with diseases and disabilities including SCI. This is because questions included in QoL measuresareoften misunderstood and wrongly interpreted by the participants of the study. For instance, one study conducted in the Netherlandslooked at QoL in people with small-cell lung cancer during their palliative care using the European Organisation for Research and Treatment of Cancer Core QoL Questionnaire (EORTC QLQ-C30). In this study, the researchers interviewed participants after they had completed the questionnaire to better understand how they interpreted the questions. This study highlighted the limitations of the QoL questions and stated that "*Patients responded in unexpected ways: by focusing on one aspect of the question, by taking the wording of the question literally, and by ignoring or excluding certain activities that they could not perform"* (pg 552) [128]. Results from this study suggest that, responses from the participants show less limitations in QoL than they were actually experiencing. They concluded that the EORTC QLQ-C30 questionnaire may not be valid in this context and not be capturing participants' real QoL [128].Other studies also highlight similar findings and indicate that people's own assessments of their QoL may differ from a formal evaluation conducted by a clinician or other[117, 129].

One study in Indonesia (a LMIC comparable to Bangladesh) reported that the concept of QoL was not easily understood by people with SCI. Rather the people with SCI were more comfortable with the words "*life satisfaction*" and "*happiness*" [130]. This study highlighted the need to ensure that QOL assessments capture concepts that are meaningful to people from different countries and cultures.Our own retrospective and prospective longitudinal study followed up people with SCI two years after discharge from a hospital in Bangladesh.

This study looked at QoL of people with SCI in Bangladesh. QoL was assessed using the SF12.The study found a low QoL but not as low as might be expected for people living with a SCI in a country like Bangladesh[36]. These results were surprising and need to be further investigated. One possible explanation is that the results reflect survival bias. That is, those with a poor QoL died before the two years leaving only those with a better QoL in the study. Alternatively, it may be that QoL in Bangladesh with a SCI is not as poor as one may expect. A third explanation is that participants were not understanding the questions or interpreted the questions and QoL in a different way to what was expected. All these issues require further investigation and some of them are further explored in my cohort study.

2.12 Summary of the problem and my thesis

In summary, secondary complications are very common for people with SCI after they are discharged from hospital in Bangladesh. These can have serious consequences on the lives of people with SCI and further compromise their QoL. In addition, they cause misery and adversely affect people's abilities to perform activities of daily living. For example, secondary complications make it difficult to work, participate in social events, and spend meaningful quality time with family and friends. Secondary complications may also incur enormous financial burden on people with SCI and their families. Secondary complications, particularly pressure ulcers, are also a major cause of premature death following SCI in Bangladesh. In HICs there are well established community-based health care facilities, but unfortunately these services do not exist in LMICs and there is little evidence about the effectiveness of any alternate services. Community-based advice, education and support may improve health status and prevent premature deathfor people with SCI in Bangladesh. Any model of care needs to be easily accessible, cost effective and evidence based. I

hypothesised that a telephone-based follow-up (currently available in many HICs) may be a suitable option for supporting people with SCI once they are discharged from hospital in Bangladesh because it is a low-cost option. Moreover, people with SCI can easily access telephones.

This thesis includes two large studies to address the above major challenges for people with SCI in Bangladesh: a cohort study and a RCT. The cohort study was conducted to provide empirical evidence about the situation (health status and quality of life) of people with SCI in Bangladesh. The cohort study also investigated five-year survival following SCI and developed a prediction model to identify people with SCI who are likely to die within five years of discharge from hospital in Bangladesh. The clinical trial (the CIVIC trial) was designed to determine whether a low-cost community-based model of care could reduce complications and prevent premature death in people with SCI in Bangladesh. I also looked at levels of impoverishment using the baseline data from the CIVIC trial. In addition, I have used a mixed methods approach to better understand the intervention that was provided as part of the CIVIC trial.

SECTION 2: THE COHORT STUDY

Chapter 3 Cohort study to determine five-year survival

A cohort study to identify people with spinal cord injuries who are likely to die within five years of discharge from hospital in Bangladesh. This study has been published in a peer-reviewed journal and is presented in its published format.

Published manuscript

Mohammad Sohrab Hossain, Lisa A. Harvey, Md. Shofiqul Islam, Md. Akhlasur Rahman, Joanne V. Glinsky, Robert D. Herbert. A prediction model to identify people with spinal cord injury who are at high risk of dying within five years of discharge from hospital in Bangladesh. Spinal Cord (2019) 57:198–205.

Conference proceedings:

This study has been presented at four conferences. It appears in the conference proceedings as:

- Hossain MS et al. (2018). A prediction model to identify those with spinal cord injury likely to die within five years of discharge from hospital in Bangladesh. Asian Spinal Cord Network, Yangon, Myanmar.
- M Sohrab Hossain, Lisa A Harvey, M ShofiqulIslam, M Aklhas Rahman, Joanne V Glinsky, Robert D Herbert (2019). A prediction model to identify those with spinal cord injury likely to die within five years of discharge from hospital in Bangladesh. International Spinal Cord Society Conference, Nice, France.
- MS Hossain, MS Islam, MA Rahman, RD Herbert, JV Glinsky, LA Harvey (2019). A prediction model to identify those with spinal cord injury likely to die within five

years of discharge. World Confederation for Physical Therapy Conference, Geneva, Switzerland.

- MS Hossain, Lisa A Harvey, Islam MS, Rahman MA, Joanne V Glinsky, Robert D Herbert (2019). A prediction model to identify those with spinal cord injury likely to die within five years of discharge from hospital in Bangladesh. Asian Spinal Cord Network conference, Kuala Lumpur, Malaysia.

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We confirm that Mohammad Sohrab Hossain has made the following contributions for this paper:

- Conception and design of the research including literature search
- Collection of data
- Analysis and interpretation of the findings
- Writing the manuscript, critical appraisal of content and response to reviewers

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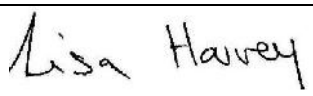
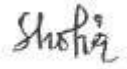
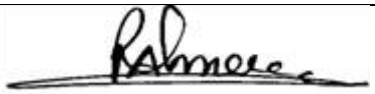
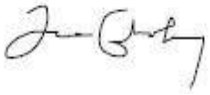
Lisa A. Harvey	
Md. Shofiqul Islam	
Md. Akhlasur Rahman	
Joanne V. Glinsky	
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ARTICLE

A prediction model to identify people with spinal cord injury who are at high risk of dying within 5 years of discharge from hospital in Bangladesh

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Abstract

Study design Mixed retrospective and prospective cohort study.

Objectives To determine 5-year survival after hospitalisation with spinal cord injury (SCI) in Bangladesh and to develop a prediction model to identify people at high risk of dying within 5 years.

Setting Bangladesh.

Methods Medical records were used to identify people with SCI admitted to a hospital in Bangladesh in 2011. Participants or their family members were contacted >5 years after discharge to determine vital status or date of death. Survival from time of discharge was estimated with Kaplan–Meier curves. A linear model of the log odds of death within 5 years of discharge was constructed and internally validated.

Results Of the 345 people who were admitted and survived to discharge in 2011, 342 (99%) were accounted for 5 years later: 74 (22%) had died (survival = 78%; 95% CI 74–82%). Sixty nine of the 223 participants who were wheelchair-dependent at discharge had died (survival = 69%; 95% CI 62–75%). A parsimonious model predicted survival as a function of age and mode of mobility at discharge (wheelchair-dependent or ambulant). The odds of dying increased by a factor of 1.6 (95% CI, 1.3–2.0) with every decade of age and by a factor of 12.6 (95% CI, 4.8–32.9) if wheelchair-dependent. The model had good calibration and discrimination.

Conclusion The risk of dying after discharge from hospital with SCI in Bangladesh is high, especially among older, wheelchair-dependent people. A simple prediction model discriminates those at high risk of dying within 5 years.

Introduction

It is widely assumed that survival after spinal cord injury (SCI) in low-income and middle-income countries (LMICs) is poor [1, 2], but this assumption is based on sparse evidence. Two systematic reviews have examined survival following SCI [2, 3]. These reviews reported the results of 10 primary studies that provided estimates of 1-year survival ranging from 79% to 100% and estimates of 5-year survival ranging from 85% to 96%. Most of the primary studies included in these reviews were population-based studies conducted in high-income countries (HICs).

Few studies have estimated survival after SCI in LMICs. One retrospective study found that 5-year survival measured from time of injury of 490 patients with traumatic SCI referred to a rehabilitation centre in Southern India was 86% [4]. Another retrospective study of 422 patients with traumatic SCI admitted to one of the two hospitals in Nigeria found that 6-month survival measured from time of admission to hospital was 66% [5, 6]. However, both studies excluded patients who were not followed up after discharge, potentially biasing the estimates of survival. A study conducted in Brazil recently reported an 83% survival rate in a cohort of 343 patients discharged from hospital with a mean (SD) follow-up time of 4.8 (3.3) years [7]. The

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5-year survival rate was 82% (estimated from the Kaplan–Meier curve).

In 2014, we retrospectively identified all people ($n = 371$) admitted in 2011 with a recent SCI to a hospital in Bangladesh that specialises in care of people with SCI. Of those discharged alive from hospital, 97% were followed up at least 2 years from discharge. Two-year survival, measured from the time of discharge, was 83% [8]. The present study reports 5-year survival data from the same cohort.

Prediction models that identify those people most likely to die soon after discharge could be used to inform life plans and to target provision of preventive interventions. Studies conducted in HICs show that age, gender and neurological loss are strong predictors of survival [3]. It is not known whether the same factors are strong predictors of survival in LMICs.

The aims of this study were to determine 5-year survival of people with SCI discharged from a specialised SCI hospital in Bangladesh and to develop a simple prediction model that could be used at discharge to identify those at high risk of death within 5 years.

Methods

The study was a mixed retrospective and prospective longitudinal cohort study [8]. Ethical permission was received from the Centre for Rehabilitation of the Paralysed Ethics Committee (approval number CRP-R&E-0401-218) prior to the commencement of the study. Informed consent was received from living participants. If potential participants had died, consent was obtained from close family members. The study was conducted in accordance with the Declaration of Helsinki Principles.

The cohort has been previously described [8]. In brief, the cohort was drawn from patients admitted with an SCI to the Center for the Rehabilitation of the Paralysed (CRP), Bangladesh in 2011. Patients were excluded from the cohort if they sustained their injury >1 year prior to the date of admission or if they died prior to discharge. The CRP is the only specialised centre for people with SCI in Bangladesh. It admits approximately 390 patients with recent SCI each year. Most patients are admitted within a few days of injury but some are referred from other hospitals up to 6 months after injury. The initial cohort was retrospectively identified from three sources that were cross-checked. The first source was hospital admission records, the second was the social welfare department's records and the third was the detailed day-to-day medical files of admitted patients. The use of three sources increases the likelihood that we were able to identify all patients eligible to participate in the study.

The outcome of interest was survival 5 years after discharge from the CRP. Five-year survival was ascertained by telephoning participants between November 2017 and May 2018, at least 5 years after discharge. If a participant could not be contacted by telephone, immediate family members were telephoned to either obtain the contact information of the participant or to verify that the participant had died and to ascertain the date of death. When it was not possible to contact participants or their families by telephone, a home visit was conducted.

Five candidate predictors of survival were measured at discharge. We only considered as candidate predictors those variables that were routinely measured and recorded prior to discharge and that could in the future be easily collected at the time of discharge in other LMICs. Our choice of predictors was also guided by the literature and other studies from LMICs and HICs (for a summary of this literature, see Table 4 of ref. [3]) [2, 9, 10].

The candidate predictors were:

1. Type of lesion: classified as either paraplegia or tetraplegia. These data were obtained from the medical records.
2. Mobility at discharge: classified as either wheelchair-dependent or ambulant. These data were obtained by asking participants at their 2-year follow-ups the following question (in Bangla): "*On discharge, did you require a wheelchair for mobility on a daily basis*?" For participants who had died, medical records were used to determine mobility on discharge (see previous publication for details [8]).
3. Gender: determined from the medical records but checked at the 2-year and 5-year follow-ups.
4. Age: determined from the medical records.
5. Cause of SCI: classified as either traumatic or non-traumatic. This was determined from the medical records.

The candidate predictors were treated as dichotomous variables, except age which was treated as a continuous variable. The American Spinal Injuries Association Impairment Scale was not used as a candidate predictor because we were concerned about relying on the medical records for these data and because this information could not be easily collected at the time of discharge, limiting the potential usefulness of predictions based on this variable.

Data analysis

Data were analysed using Stata v13.1. The cumulative probabilities of survival and hazard rates, stratified by mobility, were calculated using the Kaplan–Meier method.

To develop a prediction model, we ascertained who was alive 5 years after discharge. Univariate analyses were conducted to quantify the association between each

predictor and survival at 5 years, expressed as an odds ratio. All predictors were then entered into a multivariate logistic model. (We used a logistic model, rather than a Cox model or a parametric survival model, because Cox models do not explicitly model outcomes and because parametric survival models are less easily converted into simple, clinically useful prediction rules.) The dependent variable was death within 5 years. Of the five candidate predictors, four (type of lesion, mobility at discharge, gender and cause of injury) were binary variables; the remaining predictor (age) was a continuous variable. For parsimony, we assumed that age had a linear effect. Bootstrap variable selection was used to select predictors. This involved applying a backwards stepwise selection procedure (p to remove >0.2) to models developed on each of 1000 bootstrap replicates of the original data set. The frequency with which each of the five predictors was selected across all bootstrap replicates was tabulated. Predictors that were retained in at least 80% of the bootstrap samples were included in the final model.

The calibration and discrimination of the model were examined to determine how well the model performed. Calibration reflects whether the predicted probabilities correspond with observed probabilities. It was assessed with Hosmer–Lemeshow test and the user-written calibrationbelt command in Stata [11, 12]. Discrimination, which reflects how well the model distinguishes between people who did and did not die within 5 years of discharge, was quantified with the area under the Receiver Operator Curve (AUC).

Naive estimates of discrimination were obtained by applying the prediction model to the original data set. Optimism-corrected estimates of discrimination were obtained by calculating, in each of the 1000 bootstrap replicates, the degree of optimism (i.e., the difference between the discrimination of the model applied to the bootstrap sample on which the model was developed and the discrimination of the model applied to the original sample) and then subtracting the mean optimism from the naive estimate [13].

Results

Survival

Three hundred and sixty eight people were admitted to CRP with recent SCI in 2011. Of these, 345 survived until discharge and constituted the inception cohort. The baseline characteristics of the cohort are shown in Table 1. Two hundred and twenty three participants were wheelchair-dependent at the time of discharge. (See the legend of Table 1 for details about the small discrepancies between this paper and our previous publication [8].) All but three participants were accounted for at the 5-year follow-up. That is, 342/345 participants (99%) contributed survival data until they died or were followed up. Median follow-up time was 6.1 years (interquartile range (IQR), 5.6–6.4 years) and total person-time of follow-up was 1815 years.

Seventy four participants died within 5 years of discharge. Five-year survival from time of discharge was 78% (95% confidence interval (CI), 74–82%). The mortality rate was 0.04 deaths per person-year (95% CI, 0.04–0.56; Fig. 1). The 5-year survival for those who were wheelchair-dependent was 69% (95% CI, 62–75%), whereas 5-year survival for those who were ambulant was 96% (95% CI, 90–98%; Fig. 1). The hazard of dying, determined from the whole cohort, was slightly higher in the first few months after discharge but was nearly constant thereafter.

Table 1 describes the common causes of death. The most common causes of death were sepsis secondary to pressure ulcers ($n = 31$; 42%) and respiratory-related problems ($n = 11$; 15%).

Prediction model

The results of the univariate and multivariate analyses are shown in Table 2. The variable selection procedure dropped gender, cause of SCI (traumatic or non-traumatic) and type of lesion (tetraplegia or paraplegia) from the model. The final multivariate model therefore included mobility at discharge and age. Both these variables were included in all bootstrap replicates. In univariate analyses, the odds of dying within 5 years among patients who were wheelchair-dependent was 10.5 (4.1–26.9) times the odds of dying within 5 years among patients who were ambulant. The odds of dying within 5 years increased by a factor of 1.5 (1.2–1.8) with every decade of age. In the multivariate analyses, the corresponding odd ratios were 12.6 (4.8–32.9) and 1.6 (1.3–2.0). Fig. 2 shows the predicted probability of survival at 5 years as a function of age and mobility at discharge.

The prediction model differentiated quite well between participants who survived and who did not. Fig. 3 shows the distributions of the predicted probabilities of surviving for participants who did and did not survive to 5 years. The naive estimate of the AUC was 0.79 and the optimism-adjusted estimate of the AUC was 0.78. The prediction model also appeared to be reasonably well calibrated. Hosmer–Lemeshow test was not statistically significant ($p = 0.81$). Fig. 4 shows that the observed probability of dying within 5 years was similar to the predicted probability of dying within 5 years. This was true at all levels of predicted probability of dying.

Table 1 Characteristics of participants included in the study

	All participants[a]	Alive at 5 years[b]	Dead at 5 years[c]	Lost to follow-up
Count, *n* (%)	345	268	74	3
Gender, *n* (%)				
Female	39 (11%)	31 (12%)	8 (11%)	—
Male	306 (89%)	237 (88%)	66 (89%)	3 (100%)
Diagnosis, *n* (%)				
Paraplegia	212 (61%)	171 (64%)	38 (51%)	3 (100%)
Tetraplegia	133 (39%)	97 (36%)	36 (49%)	—
Cause of SCI				
Traumatic	327 (95%)	256 (96%)	69 (93%)	2 (67%)
Non-traumatic	18 (5%)	12 (4%)	5 (7%)	1 (33%)
Mobility at discharge, *n* (%)				
Ambulant	122 (35%)	116 (43%)	5 (7%)	1 (33%)
Wheelchair-dependent	223 (65%)	152 (57%)	69 (93%)	2 (67%)
Mobility and diagnosis, *n* (%)				
Ambulant and paraplegia	74 (21%)	68 (25%)	5 (7%)	1 (33%)
Ambulant and tetraplegia	48 (14%)	48 (18%)	—	—
Wheelchair-dependent and paraplegia	138 (40%)	103 (39%)	33 (44%)	2 (67%)
Wheelchair-dependent and tetraplegia	85 (25%)	49 (18%)	36 (49%)	—
Age (years), median (IQR)[d]	34 (25–44)	30 (22–40)	40 (32–50)	30 (30–38)
Time from injury to admission (days), median (IQR)	12 (4–35)	12 (3–35)	12 (5–37)	33 (1–68)
Length of hospital stay (months), median (IQR)	3.2 (1.9–4.4)	3.2 (2.0–4.4)	3.3 (1.5–4.5)	4.5 (3.9–5.3)
Cause of death, *n*				
Pressure ulcer	—	—	31	—
Respiratory related	—	—	11	—
Other	—	—	8	—
Unknown	—	—	24	—

[a]Our previous publication [8] involving the same cohort indicated that the number surviving to discharge was 350. The discrepancy of five people is because two people who we had been unable to find in our previous publication were found to have died prior to discharge. In addition, three people who were previously included were found to have not met the inclusion criteria (their injuries were >1 year prior to admission to CRP)

[b]Includes seven people who were alive 5 years after their discharge dates but died by the time they were contacted for follow-up

[c]Includes one participant who is known to have died but whose date of death was not known

[d]Some participants' date of births were estimated because they did not know their date of birth

Discussion

This study provides estimates of survival 5 years after discharge from a specialised SCI hospital in Bangladesh. The estimates are based on a near-complete follow-up of an inception cohort. The data are valuable because of the scarcity of information from LMICs about survival after SCI [2, 3, 7].

The data show that, among people discharged from CRP after a SCI, about 1 in 20 of those who are ambulant die within 5 years, whereas 1 in 3 of those who are wheelchair-dependent die within 5 years. Overall, 78% of participants survived at least 5 years. These data might appear to be comparable with the results from HICs. For example, two recent reviews report 1-year and 5-year survival in people with SCI ranging from 79% to 100% [2, 3]. However, our estimates of survival are from time of discharge—they do not include the risk of dying prior to hospitalisation or in hospital (21 people or 5% of the original cohort died in hospital) [8]. The restriction of our cohort to those who

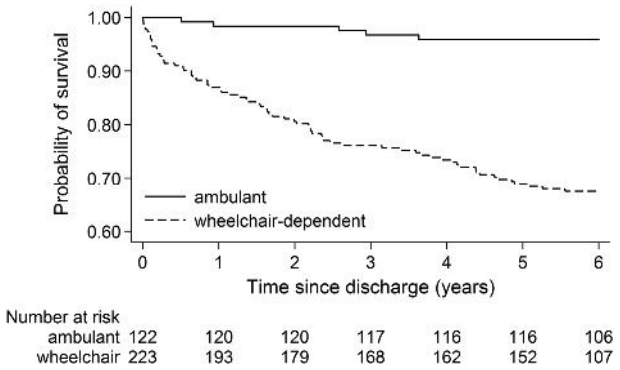

Fig. 1 Probability of survival stratified by mobility at discharge (i.e., ambulant or wheelchair-dependent)

survived until discharge probably explains why our cohort is younger (median age 34 years, IQR, 25–44 years) and less disabled than other cohorts. Older and more disabled people may not have survived long enough after injury to be admitted to CRP. While the estimates of survival from time of discharge provided by the current study are useful for post-discharge planning, estimates of survival from time of injury or time of hospitalisation would also be useful. Such studies are difficult to conduct in LMICs because they require well-coordinated health-care systems, integrated medical records and country-wide data registries.

The most common cause of death was sepsis due to pressure ulcers. It is widely recognised that pressure ulcers are a major problem after discharge from hospital with an SCI in LMICs [1, 14]. Participants in the current cohort were provided with good education and equipment for the prevention of pressure ulcers before discharge. Thus, while the proportion of deaths in the current cohort caused by pressure ulcers was high, it may be higher in other LMICs where good education and equipment for the prevention of pressure ulcers is not routinely provided. Nonetheless, there is an urgent need to reduce mortality rates due to pressure ulcers after discharge. To this end, we are currently conducting a clinical trial ($n = 410$) in Bangladesh to determine whether 2-year mortality can be reduced following discharge by providing patients with ongoing community-based support following discharge [15, 16]. The trial will be completed in early 2020.

We identified a parsimonious model that predicted 5-year survival from just two variables: age and mobility status at discharge. This is consistent with the findings of other studies that have identified age and extent of neurological loss as the strongest predictors of survival [3]. We used mobility status as a crude measure of neurological loss because we had access to data on mobility status and because we wanted a prediction model that could be used without having to conduct a full neurological assessment at discharge. It is easier to determine mobility status on discharge than to conduct a full neurological assessment according to the International Standards for the Neurological Classification of Spinal Cord Injuries. The simplicity of the model is its strength. Health-care professionals could easily use Fig. 2 to predict a patient's probability of survival 5 years after discharge based on age and mobility status on discharge. Patients at high risk of dying might be monitored more closely and provided with additional health care. This is important for LMICs that do not have the resources to provide highly specialised and intensive follow-up care for all discharged patients. There is a suggestion that this type of prioritised follow-up is already happening in countries like Afghanistan [17].

It was interesting that type of SCI (tetraplegia or paraplegia) was not retained in the final prediction model even though type of SCI reflects neurological loss. More than half of those with tetraplegia in our cohort were able to walk and most of the people with tetraplegia who were unable to walk had low cervical injuries. This is probably because, in Bangladesh, people with high cervical lesions typically do not survive more than a few days after injury and are not commonly admitted to CRP. For this reason, there may not have been a large difference in the neurological status of people with tetraplegia and paraplegia in our cohort. This explanation was provided by others [3] who observed similar findings [18]. We did not find that gender or cause of SCI were strong predictors of mortality, even though a recent review found that mortality rates were consistently higher in men than in women and in those who sustained a non-traumatic SCI compared to a traumatic SCI [2]. This may reflect the small number of women (11%) and people with non-traumatic SCIs (5%) in our cohort. Nonetheless, our prediction model is broadly consistent with the findings of other studies that have predicted mortality from age at injury, neurological level and completeness of injury [3].

The model appears to be have an acceptable level of discrimination. The AUC of 0.78 implies that, in 78% of randomly selected pairs of study participants with discordant outcomes (pairs in which one person died within 5 years and the other did not), the person who died had the higher predicted probability of dying [19]. As a comparison, the widely used Framingham cardiovascular risk score has an AUC of 0.72–0.76 when used to predict cardiovascular events in New Zealand [20]. Estimates of discrimination were internally validated and adjusted for optimism with bootstrapping, making them more likely to apply to other samples from a similar population. Nonetheless, the model now needs to be externally validated by assessing the predictive performance of the model on samples drawn from other settings (e.g. rural hospitals) in other LMICs.

There are limitations to this study. Most importantly, the study was conducted at a single centre. Also, the cohort was identified retrospectively and some of the predictors were

Table 2 Univariate and multivariate associations between candidate predictors and survival with 95% CI

Candidate predictors	Univariate analysis	Percentage of bootstrapped samples that retained predictor	Multivariate analysis	
	Odds ratio		Odds ratio	Regression coefficients
Age (in 10-year increments)	1.5 (1.2 to 1.8)	100%	1.6 (1.3 to 2.0)	0.47 (0.27 to 0.68)
Mobility at discharge	10.5 (4.1 to 26.9)	100%	12.6 (4.8 to 32.9)	2.53 (1.57 to 3.49)
Type of lesion	1.7 (1.0 to 2.8)	71%	—	—
Gender	1.1 (0.5 to 2.5)	30%	—	—
Cause of injury	1.5 (0.5 to 4.5)	52%	—	—
Intercept	—	—	—	−5.31 (−6.67 to −3.96)

Also shown are the percentage of bootstrapped samples that retained each candidate predictor. The multivariate model was a logistic model. The dependent variable was death within 5 years of discharge. The reference groups for the binary mobility, diagnosis, gender and cause of injury variables are, respectively, ambulant, paraplegia, female and traumatic. The effect of age on log odds of death was assumed to be linear. Confidence intervals do not take account of model selection procedures

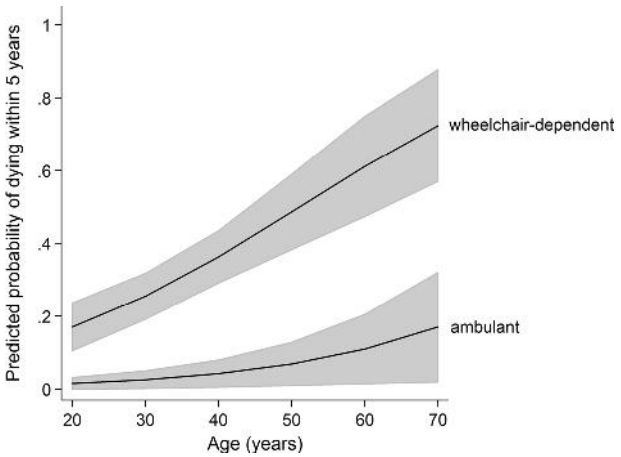

Fig. 2 Predicted probability of dying within 5 years of discharge based on age and mobility (ambulant or wheelchair-dependent) at discharge. The shaded areas are 95% CIs

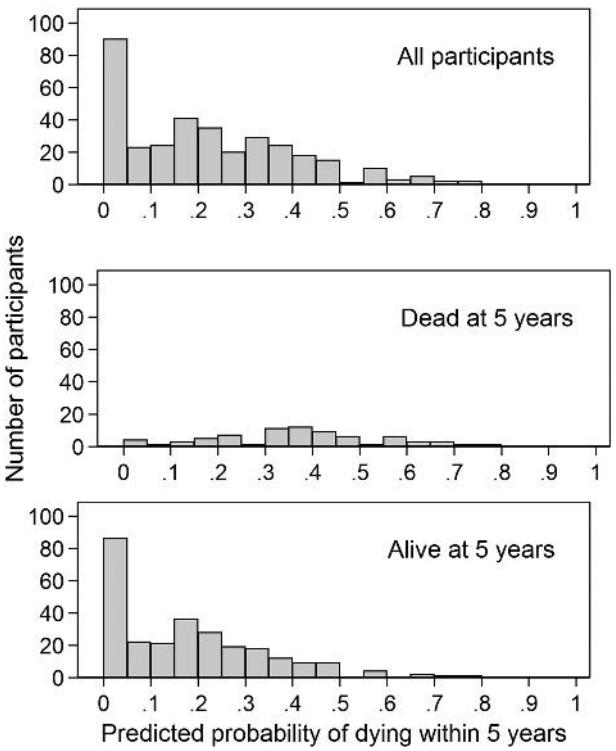

Fig. 3 Discrimination. The three histograms show the number of participants (*y* axis) as a function of the model-predicted probability of dying within 5 years (*x* axis) for all participants (top figure), those who died within 5 years (middle figure) or those who were alive at 5 years (bottom figure). If the prediction model was not discriminative, the distributions in the bottom two figures would be the same. If the model was perfectly discriminative, there would be no overlap of the two distributions. These graphs show that the model was moderately discriminative: the AUC was 0.78, meaning that in 78% of all pairs of participants (one from each distribution) the person who died had a higher predicted probability of dying than the person who did not die

collected retrospectively from medical records. As a consequence, it is possible that a small number of potentially eligible participants were not included in the cohort and that predictor data were inaccurate. In addition, we relied on family members to recall the date and cause of death because Bangladesh does not have a death registry. These limitations may have introduced small errors into the estimates of survival.

In conclusion, this study provides some of the first robust data on survival following discharge with an SCI in an LMIC. Approximately one in three patients who were wheelchair-dependent on discharge died within 5 years. We emphasise that this estimate is of survival from the time of discharge; it should not be used to predict survival from the time of injury or time of hospitalisation. A simple prediction model based on age and mobility at time of discharge coarsely discriminates between those who will and will not survive for 5 years. Individuals who are at high risk of dying within 5 years might be targeted for ongoing follow-up and care.

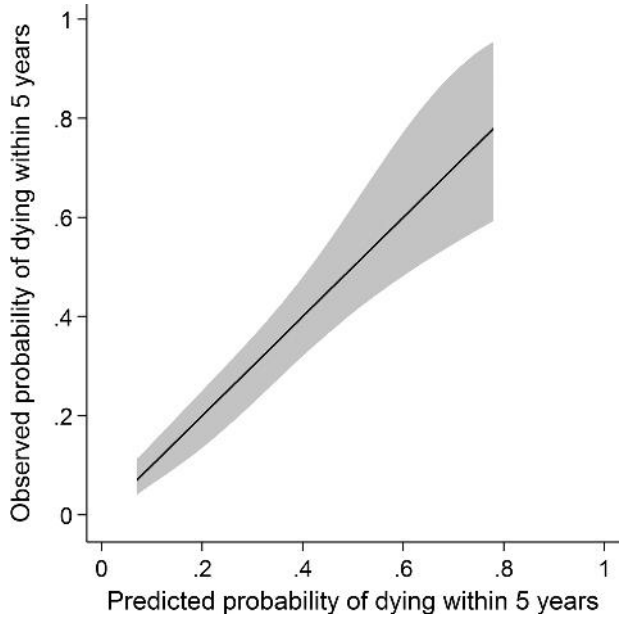

Fig. 4 Calibration of the model. Perfect calibration is represented by the diagonal line, because this is the line on which the predicted probability equals the observed probability (the line of identity). The shaded area is a calibration belt: it reflects the statistical uncertainty about the true relationship between the predicted probability of dying within 5 years and the observed probability of dying within 5 years [21]. The calibration belt includes the line of identity along its full length, meaning that there is no evidence of model miscalibration. The calibration belt only extends from predicted probabilities of 0.01–0.81 because this is the range of participants' predicted probabilities of dying within 5 years

Data archiving The authors will consider all reasonable requests for data sharing.

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Author contributions MSH conceived the research question, designed the study, collected the data, analysed the data, interpreted the data and wrote the manuscript. LAH and RDH conceived the research question, designed the study, analysed the data, interpreted the data and wrote the manuscript. MSI and MAR collected the data and contributed to the research question, the design of the study, the interpretation of the data and the write-up of the manuscript. JVG contributed to the research question, the interpretation of the data and the write-up of the manuscript.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Statement of ethics Ethical permission was received from the Centre for the Rehabilitation of the Paralysed Ethics Committee (approval number CRP-R&E-0401-218) prior to the commencement of the study. We certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers/animals were followed during the course of this research.

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Chapter 4 Cohort study to identify health status and quality of life

A mixed retrospective and prospective cohort study investigating the healthstatus, quality of life and socioeconomic situation of people with spinal cord injuries six years after discharge from a hospital in Bangladesh. This study has been published in a peer-reviewed journal and is presented in its published format.

Published manuscript

Mohammad Sohrab Hossain, Md. Shofiqul Islam, Md. Akhlasur Rahman, Joanne V. Glinsky, Robert D. Herbert, Stanley Ducharme, Lisa A. Harvey. Health status, quality of life and socioeconomic situation of peoplewith spinal cord injuries six years after discharge from a hospitalin Bangladesh. Spinal Cord (2019) 57:652–661.

Conference proceedings:

This study has been presented at a conference. It appears in the conference proceedings as:

- M Sohrab Hossain,M ShofiqulIslam, M Aklhas Rahman, Joanne V Glinsky, Stanley Ducharme, Robert D HerbertandLisa A Harvey (2019). Health status and quality of life for people with spinal cord injuries six years after discharge from a hospital in Bangladesh. International Spinal Cord Society Conference, Nice, France.

Publication statement: Statement from co-authors confirming the authorship contribution of the PhD candidate.

Mohammad Sohrab Hossain, Md. Shofiqul Islam, Md. Akhlasur Rahman, Joanne V. Glinsky, Robert D. Herbert, Stanley Ducharme, Lisa A. Harvey. Health status, quality of life and

socioeconomic situation of peoplewith spinal cord injuries six years after discharge from a hospitalin Bangladesh. Spinal Cord (2019) 57:652–661.

We confirm that Mohammad Sohrab Hossain has made the following contributions for this paper:

- Conception and design of the research including literature search
- Collection of data
- Analysis and interpretation of the findings
- Writing the manuscript, critical appraisal of content and response to reviewers

Authors' names and signatures:

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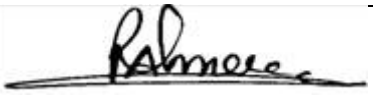
Md. Akhlasur Rahman	
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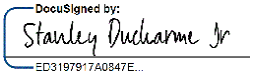
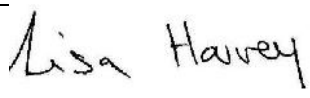
Stanley Ducharme	
Lisa A. Harvey	

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ISCoS The International Spinal Cord Society

ARTICLE

Health status, quality of life and socioeconomic situation of people with spinal cord injuries six years after discharge from a hospital in Bangladesh

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Abstract

Study design Cross-sectional analysis of a mixed retrospective and prospective inception cohort study.

Objectives To determine health status, quality of life and socioeconomic situation of people with spinal cord injuries (SCI) 6 years after discharge from a hospital in Bangladesh.

Setting Bangladesh.

Methods All patients alive 6 years after discharge from a hospital in Bangladesh were interviewed using the SF12 health survey, the SCI Secondary Conditions Scale, the Centre for Epidemiologic Studies Depression Scale (CESD), and the participation in society items of World Health Organisation Disability Assessment Schedule (WHODAS 2.0). Additional questions determined participants' socioeconomic and employment status.

Results The cohort comprised 260 participants: 145 used wheelchairs for mobility and 115 were able to walk at discharge. The median (IQR) Mental and Physical Component scores for the SF12 were 54 (49–57) and 44 (40–51) points, respectively. The median scores for the SCI Secondary Conditions Scale, CESD and WHODAS 2.0 were 8 (4–13), 7 (4–13) and 12 (6–17) points, respectively. Fourteen percent of all participants and 23% of those who used wheelchairs had a pressure ulcer at the time of interview. Forty-four percent of participants were unemployed and 65% were living below the poverty line (median (IQR) income, USD 0 (0–91)) per month.

Conclusion Many people with SCI in Bangladesh are unemployed and living in poverty with a reduced quality of life and participation. Pressure ulcers are a common complication.

Introduction

Many studies from high-income countries (HICs) have examined the physical, psychological, and social well-being of people following spinal cord injuries (SCI) [1–7]. However, there is very little information about these outcomes for people living with SCI in low- and middle-income countries (LMICs). Most of what has been described comes from small samples of convenience [8–12]. Such studies may be biased and therefore may not provide an accurate picture of the real situation. Nonetheless, they suggest that people living with SCI in LMICs face many problems and experience many complications. We sought to obtain a more accurate picture about the physical, psychological, and social well-being of people living with SCI in Bangladesh.

We previously identified all people who were discharged in 2011 with SCI from a large hospital in Bangladesh that

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specialises in the management of SCI: The Centre for the Rehabilitation of the Paralysed (CRP) [13]. This centre provides acute care and comprehensive rehabilitation services for people with SCI in Bangladesh regardless of income. Most patients are from a low socioeconomic background and are financially supported by CRP. In turn, CRP is supported by the government of Bangladesh, non-government organisations, and national and international donors. Those identified were assessed 2 years after discharge [13, 14]. We found that many people were housebound, unemployed, living in poverty and experiencing pressure ulcers. They also experienced moderate rates of depression and reported limited quality of life. The purpose of this study was to follow-up this same cohort 6 years after discharge. We were particularly interested in determining health status, quality of life and socioeconomic situation.

Methods

This is a cross-sectional analysis of a mixed retrospective and prospective inception cohort study. Medical records were used to identify all patients admitted with SCI in 2011 to CRP. At that time details of participants were also collected including cause of injury (traumatic or non-traumatic), date of injury, type of injury (tetraplegia or paraplegia) and American Spinal Injury Association Impairment Scale (AIS; according to the International Standards for Neurological Classification of SCI). Those individuals who survived until discharge comprised the initial cohort. Details about those alive at 2 years have been previously published [13, 14]. In addition, we have published a paper focusing on survival 5 years after discharge [15]. The current paper describes the health status, quality of life and socioeconomic situation of those individuals alive 6 years after discharge.

Data were collected through telephone interviews conducted between November 2017 and May 2018, a median (IQR) of 6 years (6–7) since discharge. If the participant could not be contacted by telephone, a home visit was conducted and the interview was performed in person. All interviews and questionnaires were administered in Bangla. The questionnaires were translated by two local Bangladeshi healthcare professionals who were fluent in English, except the translation of the 12-item Short Form Health Survey (SF12) and the Centre for Epidemiological Studies Depression scale (CESD) which were provided to our team by other research groups who had back translated both questionnaires. We did not use the official World Health Organisation (WHO) Bangla version of the World Health Organisation Disability Assessment Scale (WHODAS 2.0) because it was not available at the time of data collection. We did, however, subsequently cross-check our version with the official WHO Bangla version of WHOADS 2.0. The two versions were very similar although our version used less formal language in a few places. The following paragraphs outline the data that were collected.

Socioeconomic situation

Participants were asked about their current employment, income, marital status, carer arrangements, family size (total number of people living in the participant's household), current living arrangements (i.e., own house or rented), if they had conceived any children since their injury and if so how many.

The Spinal Cord Injuries Secondary Conditions Scale (SCI-SCS)

Data about secondary conditions were collected using the SCI-SCS. This is a standardised and validated 16-item questionnaire about complications such as pressure ulcers, respiratory problems, urinary and bladder incontinence, sexual dysfunction, autonomic dysreflexia, postural hypotension, spasticity, contractures and pain [16, 17]. Participants were asked to rate the 16 items according to their experiences over the last three months on a 4-point scale (0–3) where a score of zero reflects "*Not experienced in the last 3 months or not a significant problem*" and a score of four reflects "*Severe or chronic problem*". The scores for each item were totalled and expressed as a percentage of a total possible score of 48 points. A higher score reflects more complications.

Pressure ulcers

Participants were asked if they currently had a pressure ulcer. The severity of the pressure ulcer was captured in one of the questions of the SCI-SCS.

The World Health Organisation Disability Assessment Scale (WHODAS 2.0)

Community participation was captured using the participation in society items of the self-administered version of the WHODAS 2.0. The WHODAS 2.0 has been extensively used in people with SCI [18]. It has good validity and reliability [18, 19] and has been previously used in Bangladesh [10]. It comprises eight questions that seek to quantify how much people's disabilities affect their lives in the last 30 days. Each question is answered on a 5-point scale (1 = 'none', 2 = 'mild', 3

= 'moderate', 4 = 'severe' and 5 = 'extreme or cannot do'). Scores are tallied and expressed out of a total possible score of 40 points where a higher score reflects extreme problems associated with all aspects of community participation [19].

The Short Form Health Survey (SF-12)

Quality of life was assessed with the SF-12 [20]. This consists of 12 questions each graded on a 2- to 6-point scale. The Physical Component Summary and the Mental Component Summary scores were obtained using a standard algorithm developed from a US general population unadjusted for age and gender. Scores were standardised so that a score of 50 represents average functioning with a SD of 10 (that is, a score of 30 is equivalent to the lowest 2.5% of the American population). Higher scores reflect a better quality of life. The SF-12 has been used in Bangladesh with other clinical populations [20].

The Centre for Epidemiological Studies Depression scale (CESD)

Depressive disorders were measured with the CESD. This scale is widely used to assess symptoms of depression experienced over the preceeding two weeks as defined by the American Psychiatric Association Diagnostic and Statistical Manual [21–23]. The CESD comprises 20 questions each scored on a 4-point scale anchored at one end with '*rarely or none of the time'* and at the other end with '*most or all of the time*.' The highest possible score of 60 reflects a severe depressive disorder. Participants with scores of 16 or more are classified as having *subthreshold depressive symptoms*, *possible depressive disorders*, *probable depressive disorders* or *major depressive disorders* according to an algorithm. In addition, scores for individual questions are used to determine whether participants have symptoms in the nine different groups of sadness, loss of interest, appetite, sleep, thinking, guilt, tired, movement or suicidal ideation.

Additional questions

Participants were also asked two additional questions to capture their participation. The questions were:

(i) Have you got out of your bed in the last week (do not include getting out of bed for the toilet or shower)? If so, on how many days did you get out of bed?
(ii) Have you been out of the bounds of your home in the last week? If so, on how many days did you go out of the bounds of your home?

Analysis

A descriptive analysis was conducted. Continuous data were described as means (standard deviation, SD) or medians (interquartile ranges, IQR) if skewed. Count data were expressed as proportions. All data were stratified by mobility status at discharge.

Results

Three hundred and forty-five patients were discharged from CRP in 2011 with SCI. Eighty-one had died by the time of interview leaving 264 people alive. Of these, three were unable to be located and one was unable to speak and was therefore not interviewed. Therefore, the final cohort that was interviewed was 260 participants representing 98% of those discharged and still alive at 6 years. Table 1 provides demographic details of the 260 participants: 145 participants used wheelchairs for mobility and 115 were able to walk at discharge. The median (IQR) age at the time of injury was 30 years (22–40). One hundred and fifty-four (59%) had traumatic paraplegia and 95 (37%) participants had traumatic tetraplegia.

Table 2 provides details of the socioeconomic situations of participants. Most participants were married prior to injury and were still married 6 years after discharge although, amongst those who used wheelchairs at discharge, there was a small reduction in the proportion of participants who were married from injury to 6 years (from 68 to 55%). Prior to injury, 168 (65%) participants were the main income earners for their families but at 6 years only 89 (34%) participants were the main income earners most of whom were walking at discharge. The median (IQR) income per month of all participants at 6 years was USD 0 (0–91); 65% of all participants and 75% of those who used wheelchairs were living below the poverty line 6 years after discharge (the poverty line for Bangladesh is less than $60 per month as defined by WHO [24]).

Table 3 shows the results of the SCI-SCS, WHO-DAS 2.0, SF12, CESD, presence of pressure ulcers and the two additional questions about participation. The median (IQR) scores for the SCI-SCS, and WHODAS 2.0 were 8 points (4–13) and 12 points (6–17), respectively. The median (IQR) scores for the Physical and Mental Components of the SF-12 were 44 points (40–51) and 54 points (49–57), respectively. The median (IQR) scores for the CESD was 7 points (4–13). The CESD results are also expressed according to the number of people exhibiting symptoms of depression in each of the nine different groups and the number of people with possible, probable and major depressive episodes. Thirty-five participants (14%) had pressure ulcers at the time of interview. Figures 1 and 2 and

Table 1 Characteristics of all participants ($n = 260$). Data are means (SDs) except where indicated otherwise

	All participants ($n = 260$)	Walking at discharge ($n = 115$)	Using a wheelchair at discharge ($n = 145$)
Gender, *n* (%)			
Male	231 (89%)	98 (85%)	133 (92%)
Female	29 (11%)	17 (15%)	12 (8%)
Age at the time of injury (years), median (IQR)	30 (22–40)	35 (25–45)	28 (20–36)
AIS classification, *n* (%)			
A	116 (45%)	9 (8%)	107 (74%)
B	61 (24%)	34 (30%)	27 (19%)
C	32 (12%)	24 (21%)	8 (6%)
D	48 (19%)	45 (39%)	3 (2%)
E	3 (1%)	3 (3%)	–
Type of injury, *n* (%)			
Paraplegia, *n* (%)	164 (63%)	67 (58%)	97 (67%)
Traumatic	154 (59%)	59 (51%)	95 (67%)
Non-traumatic	10 (4%)	8 (7%)	2 (1%)
Tetraplegia, *n* (%)	96 (37%)	48 (42%)	48 (33%)
Traumatic	95 (37%)	48 (42%)	47 (32%)
Non-traumatic	1 (1%)	–	1 (1%)
Others, median (IQR)			
Follow-up time (years)	6 (6–7)	6 (6–7)	6 (6–7)
Time between injury and admission (days)	12 (4–35)	9 (3–25)	15 (4–48)
Length of hospital admission (months)	3 (2–4)	2 (2–3)	4 (3–5)

the Supplementary files show the responses to each of the questions comprising the WHODAS 2.0 and the SCI-SCS for those who were walking at discharge and those who were using a wheelchair at discharge.

Discussion

The results of this study are valuable because most of what we know about the health status, quality of life and socioeconomic situation of people with SCI living in LMICs come from cross-sectional studies of samples of convenience [8–12]. These types of studies are vulnerable to selection bias. The cohort in this study is unique because it is a representative sample of all patients admitted to a large hospital in Bangladesh with very little loss to follow-up 6 years after discharge. The most important findings from this study are that people surviving for 6 years experienced high levels of unemployment and poverty, and that pressure ulcers are prevalent.

At the time of interview, 35 participants (14%) had a pressure ulcer (Table 3). Of these, 22 (9%) reported that pressure ulcers had been a moderate or chronic problem in the preceding 3 months (Fig. 2). All but one participant with a pressure ulcer used a wheelchair for mobility at discharge. These findings probably underestimate the real problems that pressure ulcers pose in LMICs [7, 25, 26] because those who had already died ($n = 81$) or were not interviewed for other reasons ($n = 4$) may have been more likely to have experienced pressure ulcers had they been alive and included [13, 14]. Our findings may also not be reflective of the severity of the problem for most people living with SCI in LMICs because the participants in our cohort may have been better able to manage skin problems than most. Unlike many individuals from LMICs, the participants in our cohort had received comprehensive rehabilitation including education about skin care and provision of equipment for the prevention of pressure ulcers.

Complications other than pressure ulcers were less common (Fig. 2). Only 15% of participants reported muscle spasms as a moderate or chronic problem even though this was the most commonly reported problem on the SCI-SCS. This is a lower rate of complications than reported in comparable studies from LMICs [5, 26, 27] and even lower than reported from HICs [3, 7, 28–30]. Similarly, none of the participants in our cohort reported injuries secondary to loss of sensation even though others have found that up to 50% of participants experience this complication [29, 30].

Table 2 Financial and social situation for all participants ($n = 260$)

	All participants ($n = 260$)	Walking at discharge ($n = 115$)	Using a wheelchair at discharge ($n = 145$)
Marital status at time of injury, *n* (%)			
Married	188 (72%)	89 (77%)	99 (68%)
Not married	69 (27%)	23 (20%)	46 (32%)
Divorced[a]	1 (1%)	1 (1%)	–
Marital status at 6 years, *n* (%)			
Married	171 (65%)	91 (79%)	80 (55%)
Not married	72 (28%)	20 (17%)	52 (36%)
Divorced[a]	15 (6%)	3 (3%)	12 (8%)
Widowed	2 (1%)	1 (1%)	1 (1%)
Place of residence, *n* (%)			
Urban/city	20 (8%)	12 (10%)	8 (5%)
Rural/village	240 (92%)	103 (90%)	137 (95%)
Work status at 6 years, *n* (%)			
Full time employed (> 30 h per week)	102 (39%)	51 (44%)	51 (35%)
Part time employed (< 30 h per week)	21 (8%)	11 (10%)	10 (7%)
Retired	2 (1%)	2 (2%)	–
Unemployed	115 (44%)	38 (33%)	77 (53%)
Home duties	11 (4%)	8 (7%)	3 (2%)
Student	9 (4%)	5 (4%)	4 (3%)
Main income earner prior to injury, *n* (%)	168 (65%)	76 (66%)	92 (63%)
Main income earner at 6 years, *n* (%)	89 (34%)	53 (46%)	35 (24%)
Participants' income ($) per month prior to injury, median (IQR)	78 (39–117)[b]	78 (39–130)	65 (39–104)[c]
Participants' income ($) per month at 6 years, median (IQR)	0 (0–91)	52 (0–130)	0 (0–65)
Participants in poverty prior to injury, *n* (%)	84 (32%)	36 (31%)	48 (33%)
Participants in poverty at 6 years, *n* (%)	168 (65%)	60 (52%)	108 (75%)
Main carer at 6 years, *n* (%)			
Spouse	157 (60%)	79 (69%)	78 (54%)
Parent	63 (24%)	14 (12%)	49 (34%)
Others	40 (16%)	22 (19%)	18 (12%)
Number of people per household at 6 years, median (IQR)	4 (3–5)	4 (3–5)	4 (3–5)
Number of participants conceiving children after SCI, *n* (%)			
One child	25 (10%)	20 (17%)	5 (3%)
Two children	6 (2%)	6 (5%)	–

[a]These numbers only include those who declared that they were divorced. It does not include those who were living apart from their spouses

[b]$n = 252$

[c]$n = 141$

Table 3 Results of questionnaires for all participants ($n = 260$)

	All participants ($n = 260$)	Walking at discharge ($n = 115$)	Using a wheelchair at discharge ($n = 145$)
SCI Secondary Conditions Scale (%), median (IQR)	8 (4–13)	4 (2–8)	10 (8–15)
WHODAS 2.0—participation in society items, median (IQR)/40 pts	12 (6–17)	5 (0–13)	15 (10–18)
SF12, median (IQR)			
Mental	54 (49–57)	54 (52–55)	54 (45–57)
Physical	44 (40–51)	51 (44–52)	41(38–44)
CESD, median (IQR)			
Total score, /60 pts	7 (4–13)	5 (3–8)	9 (5–17)
Symptoms group of the CESD, *n* (%)			
Sadness	23 (9%)	7 (6%)	16 (11%)
Loss of interest	18 (7%)	3 (3%)	15 (10%)
Loss of appetite	3 (1%)	–	3 (2%)
Sleep	3 (1%)	1 (1%)	2 (1%)
Thinking	3 (1%)	–	3 (2.1%)
Guilt	9 (4%)	3 (3%)	6 (4.1%)
Tired	38 (15%)	9 (8%)	29 (20%)
Movement	20 (8%)	6 (5%)	14 (10%)
Suicidal ideation	6 (2%)	3 (3%)	3 (2%)
Depression subdomain scores, *n* (%)			
Total score > 15 points	54 (21%)	12 (10%)	42 (29%)
Possible major depressive episode	5 (2%)	1 (1%)	4 (3%)
Probable major depressive episode	7 (3%)	2 (2%)	5 (3%)
Meets criteria for major depressive episode	6 (2%)	2 (2%)	4 (3%)
Pressure ulcer, *n* (%)	35 (14%)	1 (1%)	34 (23%)
Out of bed			
Number of people out of bed, preceding week, *n* (%)	256 (99%)	114 (99%)	142 (98%)
Number of days out of bed, preceding week, median (IQR)	7 (7–7)	7 (7–7)	7 (7–7)
Out of home			
Number of people out of home, preceding week, *n* (%)	236 (91%)	113 (98%)	123 (85%)
Number of days out of the home, preceding week, median (IQR)	7 (7–7)	7 (7–7)	7 (3–7)

CESD Centre for Epidemiologic Studies Depression Scale, *IQR* interquartile range, *pts* points, *SCI* spinal cord injury, *WHODAS 2.0* World Health Organisation Disability Assessment Scale 2.0

These differences may in part reflect the problems of relying on self-report over the telephone. Alternatively, they may reflect the characteristics of the study participants. For instance, the two studies from LMICs included participants soon after injury before those at high risk of complications had died, and most studies (including those from HICs) have high dropout rates [9].

Participation (defined here as involvement in life situations [31]) was captured through the participation in society items of the WHODAS 2.0. The median (IQR) score was 12/40 points (6–17) indicating that participants had some problems with participation, but the level of problems that participants experienced was not as high as expected. For example, these scores are lower than those reported in

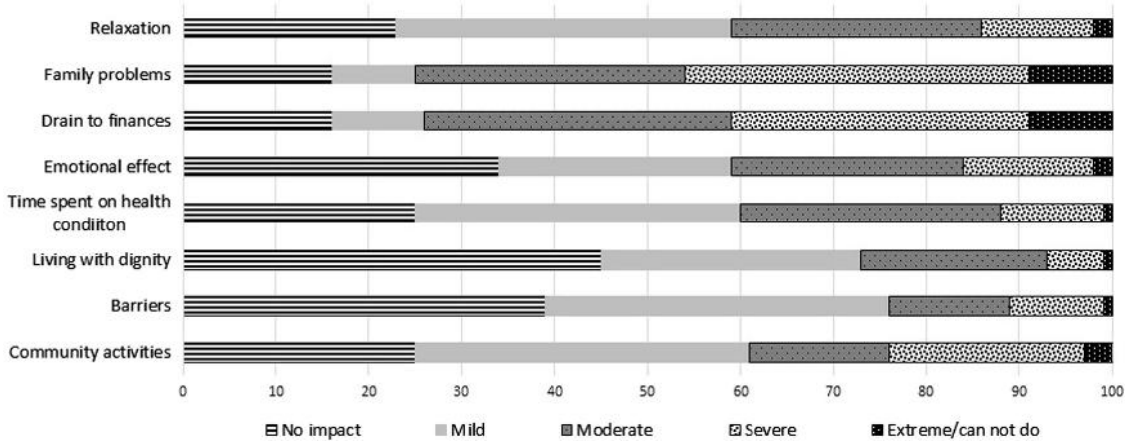

Fig. 1 Results of the participation in society items of the WHODAS 2.0 for all participants ($n = 260$). The x-axis shows the percentage of responses and the y-axis shows each of the items on the WHODAS 2.0 (see supplementry files for data divided by walking and using a wheelchair at discharge)

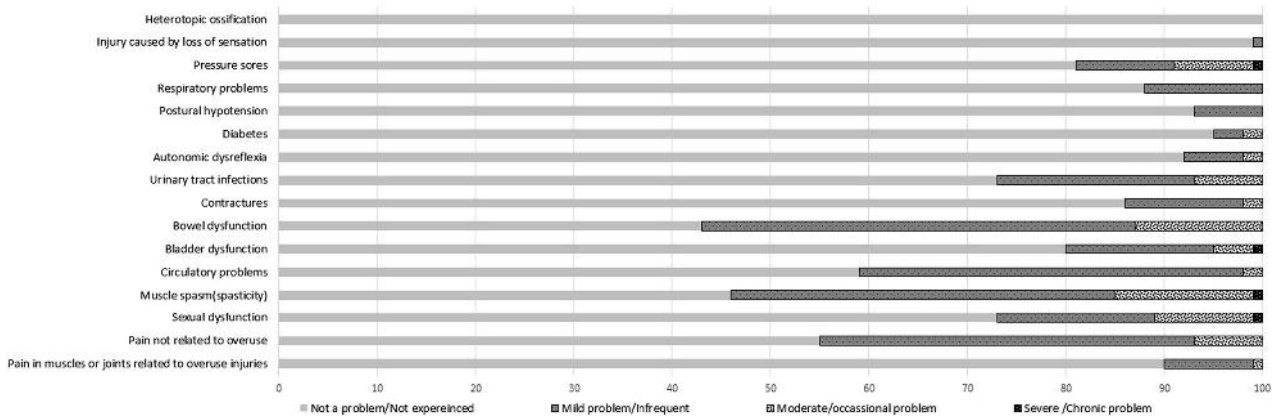

Fig. 2 Results of Spinal Cord Secondary Conditions Scale for all participants ($n = 260$). The x-axis shows the percentage of responses and the y-axis shows each of the items on the Spinal Cord Injury Secondary Conditions Scale (see supplementary files for data divided by walking and using a wheelchair at discharge)

comparable studies from Canada (mean = 14 points) [32] and Taiwan (mean = 23 points) [19]. Not surprisingly, those in our cohort who used wheelchairs at discharge reported less participation on the WHODAS 2.0 (median 15: IQR 10–18) than those who were walking at discharge (median 5: IQR 0–13) (Table 3). Two SF-12 questions also reflect participation; one asks participants if their health limits their ability to work and the other asks if health interferes with social activities. Thirty-five percent and 97% of participants who used wheelchairs indicated that they experienced limitations in these two areas, respectively. These findings were mirrored in the responses to the question about how often participants left their homes in the preceding week. Even though the median for the two groups was 7 days, suggesting good participation, the lower end of the IQR for those who used wheelchairs indicated that 25% of this group did not leave their homes more than three times in the preceding week (Table 3). These data may overestimate participation and underestimate the extent of social isolation experienced by people living with SCI in LMICs because when participants were asked if they moved outside their homes, they did not distinguish between just moving (or being moved) outside the front door of their homes and moving further afield into their communities. The results may therefore largely reflect how often people moved from inside their homes to a cooler position outside their homes during the day. Nonetheless, our data do not negate the obvious and pressing need to improve wheelchair access in these communities [8, 33, 34] as recommended in the WHO international perspectives on SCI report [35] and in The Convention on the Rights of Persons with Disabilities [36].

Limited participation was accompanied by poor scores on the SF-12 but these scores were not as low as one might expect. The poorest scores were for the physical domain in those who used wheelchairs (median 41: IQR 38–44) (Table 3). The scores for the physical domain were lower than the scores for the mental domain for both groups.

While 15% and 17% of participants indicated on the SF-12 that they accomplished less than they would like or did not perform work or activities as carefully as usual due to emotional problems (such as feeling depressed or anxious), respectively, they displayed generally low levels of depression with low CESD scores (median CESD score of 7/60 points; IQR 4–13) (Table 3). However, some participants showed signs of sadness (9%), loss of interest (7%), tiredness (15%) and agitation (8%) on these CESD symptom groups. In addition, a small number of participants had major depression (2%), probable depression (3%) or possible depression (2%) according to the American Psychiatric Association Diagnostic and Statistical Manual. Nonetheless, our findings on depression contrast the findings from HICs that report much higher rates of depression [4, 21].

A notable and alarming finding from the WHODAS 2.0 data was that 57% and 53% of participants who used wheelchairs at discharge reported that their SCI had created "severe" or "extreme" family problems and stress on their family's finances, respectively (Supplementary File 1), with 84% of participants reliant on spouses or parents as their main carers (Table 2). These findings may partly reflect that most were young married men living in large families (median number of people per household, 4: IQR 3–5) in which 65% were the main income earners prior to injury. At 6 years only 34% of participants were the main income earners and 65% lived below the poverty line (equivalent to USD 60 per month or USD 1.97 per day [24]). Not surprisingly individual income of participants fell from a median (IQR) of USD 78 (39–117) per month prior to injury to USD 0 (0–91) 6 years after injury. These data highlight the far-reaching implications of SCI for people living in LMICs and their families, and the pressing need for a focus on employment to reduce the poverty associated with SCI [36–39]. Similar findings have been reported by others who have highlighted the need for interest-free loans for people with SCI in Bangladesh [40]. The low rates of employment may also reflect discrimination and biases against people with disabilities.

The results presented here at 6 years after discharge were largely similar to the results from the same cohort 2 years after discharge [14]. For example, the median (IQR) SCI-SCS score was 8 (4–13) at 2 years and 10 (6–17) at 6 years. Similarly, the proportion of participants with pressure ulcers were similar (14 and 16%). However, there were some improvements in quality of life with a mean (SD) mental SF12 score at 2 years of 33.9 (6.4) versus mean (IQR) score at 6 years of 54 (49–57) points. Similarly, the levels of depression decreased over time from a median (IQR) of 10 (8–14) to 7 (4–13) points on the CESDS. The only marked difference was with the WHODAS 2.0 scores. At 2 years the median (IQR) WHODAS 2.0 was 24 (20–26) and at 6 years it was 12 (6–17) points, reflecting increased participation with time.

The main limitation of our study was that most data were collected through self-reported questionnaires administered over the telephone. It would have been better to have interviewed participants in their homes and verified answers in a more objective way. For instance, complications could have been better assessed through a physical examination, and participants' socioeconomic situation could have been more accurately determined through a home visit. However, sending staff all over Bangladesh is costly and expensive, particularly given the problems with travelling to rural locations. In addition, there are advantages to exploring participants' perspectives regardless of whether they align with objective assessments.

Another limitation of our study was the reliance on questionnaires developed for HICs. This was particularly problematic for the SF-12 because the scoring uses normative data from the US which may compromise the validity of the findings [41]. In addition, some questions from some of the assessments were not appropriate for all participants and some questions may have been misunderstood. For example, the SCS-SCI contains a question about sexuality but the question is ambiguous, and hence it is unclear whether it refers to sexual dysfunction or sexual dissatisfaction. Similarly, one of the questions in the SF-12 asks participants if they accomplished less than they would like. Eighty-five percent of participants answered "no". This is an unexpected finding and suggests a problem with the question for the Bangladeshi context. In addition, there are issues around cultural norms which may have discouraged participants from revealing their true experiences particularly for questions related to sexuality and depression [42]. Many of these and related issues require further exploration with unambiguous language that takes cultural norms into consideration.

All of our results may have been influenced by survival bias. That is, those who died by 6 years ($n = 81$) may not have been a random subgroup of the original cohort and may have scored differently to the others on all outcomes had they survived. Studies from HICs may not be so vulnerable to this type of bias because they have lower rates of mortality, and different underlying socioeconomic causes of premature death following SCI. Similarly, there may be fundamental differences in the neurological status of our cohort than those from HICs. For example, our cohort is younger and less disabled than most [15]. These two factors make comparisons between our results and those from HICs difficult, and may in part explain some of our surprising results particularly for depression and quality of life. Alternatively, the surprising results may reflect cultural differences between HICs and LMICs. Bangladesh is a country in which most people have strong family support

and religious beliefs. In addition, there are many other cultural factors that feed into people's interpretation and acceptance of their situations. For example, our impression is that people living in rural Bangladesh are often very accepting of a change in circumstances. These factors together may make people living with SCI in Bangladesh more resilient than is often assumed and may help maintain quality of life and help protect against depression after SCI. This hypothesis is highly speculative but other researchers working in LMICs have also noted that those with severe injuries, disabilities and disadvantage do not exhibit the high levels of depression and low levels of quality of life that would be expected from similar cohorts in HICs [9, 43]. These researchers have suggested that cultural, religious and family differences between LMICs and HICs could explain these findings [35, 44, 45]. This interpretation also aligns with the beliefs of some cross-cultural psychologists who argue that quality of life and other aspects of subjective well-being are highly influenced by culture [42, 46]. We acknowledge, however that this interpretation is not easily reconciled with the observation of high rates of depression following the onset of leprosy and stroke in Bangladesh [47], and that there may be many other explanations including problems with the scales used to assess quality of life and depression. Clearly, more work is required in this area and it is important that conclusions regarding depression in LMICs are based on additional studies which consider all factors.

This study provided a snapshot of the health status, quality of life and socioeconomic situation of a representative sample of people living with SCI 6 years after discharge from a hospital in Bangladesh. The key findings from this study are that these people experience high levels of unemployment and poverty. Quality of life is reduced and there is some depression. Participation is restricted by the physical environment, and pressure ulcers are a common complication. It is hoped that this study will draw additional attention to the needs of people with SCI living in LMICs. Key issues that need addressing are increased opportunities for employment, better wheelchair access in communities, and models of care to help manage pressure ulcers in the community.

Data archiving

All reasonable requests for access to the original data upon which this paper is based will be considered.

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Author contributions MSH conceived the research question, designed the study, collected the data, analysed the data, interpreted the data and wrote the manuscript. LAH and RDH conceived the research question, designed the study, analysed the data, interpreted the data and wrote the manuscript. MSI and MAR collected the data and contributed to the research question, the design of the study, the interpretation of the data and the write-up of the manuscript. JVG and SD contributed to the interpretation of the data and the write-up of the manuscript.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Statement of ethics The study received ethical approval (CRP-R&E-0401-218) from CRP and was conducted in accordance with the Declaration of Helsinki. Participants provided informed consent. We certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during the course of this research.

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SECTION 3:THE CIVIC TRIAL

Chapter 5 Statistical analysis plan of the CIVIC trial

Community-based interventions to prevent serious complications following spinal cord injury in Bangladesh: The CIVIC trial statistical analysis plan.This study has been published in a peer-reviewed journal and is presented in its published format.

Published manuscript

Robert D. Herbert, Lisa A Harvey, Mohammad S Hossain, Md. Shofiqul Islam, Qiang Li, Laurent BillotandThe CIVIC Trial Collaboration.Community-based interventions to preventserious complications following spinal cordinjury in Bangladesh: the CIVIC trial statisticalanalysis plan. BMC Trials (2019) 20:238.

Publication statement: Statement from co-authors confirming the authorship contribution of the PhD candidate.

Robert D. Herbert, Lisa A Harvey, Mohammad S Hossain, Md. Shofiqul Islam, Qiang Li, Laurent BillotandThe CIVIC Trial Collaboration.Community-based interventions to preventserious complications following spinal cordinjury in Bangladesh: the CIVIC trial statisticalanalysis plan. BMC Trials (2019) 20:238.

We confirm that Mohammad Sohrab Hossain has made the following contributions for this paper:

- Conception and design of the statistical analysis plan
- Feedback on the draft manuscript
- Critical appraisal of content

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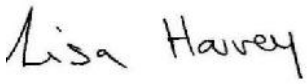
Lisa A Harvey	
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Trials

UPDATE Open Access

Community-based interventions to prevent serious complications following spinal cord injury in Bangladesh: the CIVIC trial statistical analysis plan

Robert D. Herbert[1], Lisa A. Harvey[2*], Mohammad S. Hossain[2], Md. Shofiqul Islam[3], Qiang Li[4], Laurent Billot[4] and The CIVIC Trial Collaboration[2]

Abstract

Background: People who sustain spinal cord injuries in low- and middle-income countries are vulnerable to life-threatening complications after discharge. The aim of this trial is to determine the effect on all-cause mortality of a sustainable model of community-based care provided over the first 2 years after discharge.

Methods and analysis: The CIVIC trial is a single centre, parallel group trial with concealed and stratified randomisation. The protocol has been previously published (*BMJ Open* 2016;6:e010350). This paper provides the accompanying detailed statistical plan. In total, 410 people with recent spinal cord injury who are wheelchair dependent and about to be discharged from the Centre for the Rehabilitation of the Paralysed in Bangladesh are randomised to intervention or control groups. Participants assigned to the intervention group receive a model of community-based care in which a case manager provides ongoing telephone-based support and visits participants in their homes over a 2-year period. Participants assigned to the control group receive usual care which may involve a follow-up phone call or a home visit. The primary outcome is all-cause mortality at 2 years as determined by a blinded assessor (Bangladesh does not have a death registry). The primary effectiveness analysis will compare Kaplan-Meier survival curves (time from allocation to death) in the intervention and control groups using the log-rank test (two-tailed $\alpha = 0.05$). Participants will be censored at the time they were last known to be alive or at the time of the follow-up assessment. Recruitment finished in March 2018 and the last assessment will be conducted in March 2020.

Discussion: The CIVIC trial will provide unbiased and precise estimates of the effectiveness of a model of community-based care for people with spinal cord injuries in Bangladesh. The results will have implications for provision of health services for people with spinal cord injuries and other conditions that cause serious disability in low-income and middle-income countries.

Trial registration: ANZCTR, ACTRN12615000630516, U1111-1171-1876. Registered on 17 June 2015.

Keywords: Spinal cord injury, Community-based rehabilitation, Clinical trial, Secondary complications

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Background

While it is apparent that spinal cord injuries are common in low- and middle-income countries, robust incidence data are scarce [1–4] and robust population-based data on mortality rates following spinal cord injuries in low- and middle-income countries are not available. A longitudinal cohort study of a representative sample of 350 people with spinal cord injury who survived until discharge from a specialised hospital in Bangladesh found that one in five people who were wheelchair-dependent at discharge had died within 2 years [5]. Most died from complications related to pressure ulcers. The problems of pressure ulcers in low- and middle-income countries is widely documented [1, 6].

Our research team, which includes health professionals and health service providers based in Bangladesh, has proposed an inexpensive model of community-based care for people discharged from hospital with spinal cord injury. The objective is to increase survival after discharge. The model of care involves assigning a case manager to each person with spinal cord injury at the time the person is discharged from hospital. The case manager telephones the person each fortnight in the first year following discharge and each month in the second year, and visits the person in their home three times over the first 2 years. At each point of contact, the case manager screens for complications and provides the person and their families with ongoing advice, support, and education. There is a particular focus on preventing and treating pressure ulcers.

The trial commenced in July 2015 and the last participant was randomised in March 2018. The trial is due for completion in March 2020. The protocol for the CIVIC trial has been published [7]. The purpose of this paper is to provide the detailed statistical analysis plan and allow future readers of the trial report to confirm that the trial has been analysed according to a pre-specified plan. The study will include a formal cost-effectiveness analysis and a process analysis [8], but they are not described in this statistical analysis plan.

Methods/design

Aim

The primary aim of the CIVIC trial is to determine whether a sustainable community-based model of care reduces all-cause mortality 2 years after discharge in people with spinal cord injury in Bangladesh. Secondary aims are to determine whether this model of care reduces the burden of complications, reduces the prevalence and severity of pressure ulcers, reduces depression, enhances quality of life, independence, and participation, and is cost-effective.

Design

The trial is a two-arm parallel pragmatic randomised trial. It is investigator-driven. The trial is managed by George Clinical, India.

Setting

The trial is being conducted at the Centre for the Rehabilitation of the Paralysed in Savar, Bangladesh. This is a not-for-profit hospital that provides care and rehabilitation for people with spinal cord injuries. It admits approximately 350 people with recent spinal cord injuries each year making it one of the largest spinal injury units catering for recently injured people with neurological loss in Asia and the only specialised centre for spinal cord injuries in Bangladesh.

Participants

In total, 410 people have been randomised to the CIVIC trial. Participants are people who, at the time of randomisation, had been admitted to the Centre for Rehabilitation of The Paralysed with an acute spinal cord injury, and who were over the age of 16 years and were wheelchair-dependent. Potential participants were excluded if walking was their usual mode of ambulation or they planned to move to another country.

Procedures

The full protocol can be found elsewhere [7]. In brief, participants were randomised in a 1:1 ratio to an intervention or control group using randomly permuted blocks. The allocation sequence was stratified by level of lesion (paraplegia or tetraplegia) using the user-written ralloc command in Stata [9]. Participants in the intervention group receive fortnightly phone calls from a case manager in the first year after discharge and monthly phone calls in the second year. They also receive three home visits over the 2 years and up to AUD $80 to spend on necessary items. Participants in the control group receive standard care only. Standard care may consist of a phone call or a home visit.

The primary outcome is survival (all-cause mortality) at 2 years after randomisation determined by a blinded assessor. Bangladesh does not have a death registry, and so the date of death is confirmed by interviewing next of kin or carers at 2 years. Wherever possible, independent corroboration of the date of death is obtained. There are a number of secondary outcomes, including burden of complications, prevalence and severity of pressure ulcers, depression, quality of life, independence, and participation. Questionnaires are administered in the Bangla language under the guidance of a blinded assessor.

Data management and data integrity

Data are collected in paper format, transferred to George Clinical India, and entered into an electronic database (RedCap). Electronically transcribed data are stored and managed by the Data Management Division of George Clinical India. Data are double-entered. Automated checks are conducted to detect data entry errors. Data

queries are emailed to the site coordinator and stored on the database.

Sample size

The sample size of 410 gives a better than 80% probability of detecting an increase in survival from 83% to 93% at 2 years with a two-sided log-rank test, uniform follow-up time of 2 years, loss to follow-up in both groups of 15% at 2 years, and α of 0.05.

Allowance has been made in sample size calculations for a single interim analysis conducted when the first 205 participants have been followed up (i.e. at an information fraction of 205/410 = 0.5) using the O'Brien-Fleming alpha spending function.[1]

Stopping rules

A recommendation to terminate the trial early for effectiveness will only be made if the Data Monitoring Committee determines both that there is proof beyond reasonable doubt that the intervention is clearly indicated (that is, the net benefit—weighing the health benefits against costs, risks, and inconveniences—clearly favours intervention) and that the trial provides sufficiently strong evidence of benefit that it might reasonably be expected to influence patient care. A recommendation to terminate the trial early for safety will only be made if the Data Monitoring Committee determines there is proof beyond reasonable doubt that the intervention causes an unacceptable net harm. The trial will not be terminated on the grounds of futility.

A recommendation to terminate the trial will be informed both by a formal interim statistical analysis and other considerations, including the pattern of effects across all effectiveness and safety outcomes. The statistical criterion for termination of the trial is that the confidence interval for a beneficial effect includes only clinically important beneficial effects, or that the confidence interval includes only clinically important harmful effects. A statistically significant test of the null hypothesis of no effect will not, on its own, be grounds for termination of the trial. A formal interim analysis will be conducted by an independent statistician and presented to the Data Monitoring Committee after outcomes have been obtained from approximately 205 participants. The Steering Committee will not be informed of the results of the unblinded interim analysis unless a recommendation is made to terminate the trial.

Statistical analysis

The analysis will be conducted by statisticians from the George Institute using SAS. Efficacy analyses will be independently replicated by one of the investigators using Stata. Any discrepancies between the two analyses will be resolved by consensus.

General principles

Analyses will be conducted on an intention-to-treat basis. Hypothesis tests will be conducted but the interpretation of the trial findings will consider point estimates of effects and their confidence intervals. Hypothesis tests will be two-tailed tests (alpha = 0.05). Confidence intervals and p values will not be adjusted for multiplicity, but interpretation of secondary outcomes will include consideration of multiplicity.

Trial profile

The flow of participants through the study will be reported in a CONSORT flow diagram. Reasons for exclusion will be provided.

Description of study sample at baseline

The study sample will be described in detail using data obtained prior to randomisation. Formal between-group comparisons will not be made on baseline variables.

Adherence

Data will be obtained on adherence to the trial protocol. For the primary trial report, adherence will be reported as the number and duration of calls received or the number of home visits made and these will be expressed as a proportion of the number of calls or home visits specified in the protocol. The denominator of this proportion will take into account that calls and home visits cannot occur after a participant has died.

Efficacy analysis: primary outcome

Primary analysis

The primary effectiveness analysis will compare time to death from any cause in the intervention and control groups. Kaplan-Meier survival curves will be compared using the log-rank test (two-tailed α = 0.05). Participants will be censored at the time they were last known to be alive or at the time of the follow-up assessment (intended to be 2 years after randomisation), whichever is earlier.

Size of effect

The primary estimates of the size of the effect of the intervention will not be adjusted for covariates. Effect estimates will be expressed as:

- a hazard ratio calculated from a simple Cox model (containing a term for intervention) with 95% confidence limits.
- both the difference and ratio of the restricted mean survival times of the intervention and control groups at 2 years, with 95% confidence limits. Restricted mean survival times will be estimated by numerical integration of the Kaplan-Meier curves up to 2 years. Confidence intervals will be generated

using the procedures described by Cronin and colleagues [10].
- the difference in risk of all-cause mortality at 2 years, with 95% confidence limits. The confidence interval will be bounded by Wald (asymptotic) confidence limits based on the normal approximation.

If there is any discrepancy between the log rank test used in the primary analysis and the test of the size of effect implicit in the confidence intervals for estimates of the size of the effect, the log rank test will be used as the primary test of effect.

Sensitivity analyses

Additional tests will be conducted using:

- a Cox model adjusted for level of lesion (tetraplegia or paraplegia).
- a combined test of restricted mean survival times adjusted for level of lesion (tetraplegia or paraplegia) [11].
- a test of the difference in all-cause mortality at 2 years adjusted for level of lesion (tetraplegia or paraplegia) using log-binomial regression.

Missing data handling

For the analysis of time to death missing data will not be imputed. Instead, participants with an unknown vital status at 2 years will be censored when they were last known to be alive. For the comparison of all-cause mortality at 2 years, if more than 5% of participants have an unknown vital status, a further sensitivity analysis will examine the treatment effect under all possible outcomes (dead or alive) for all participants with a missing data endpoint [12]. Within each treatment arm, if we denote as m_k (k = 0,1) the number of participants with a missing outcome, we will run $m_k + 1$ possible scenarios from the most to the least favourable where:

- Scenario 0: 0 participants died
- Scenario 1: 1 participant died
- Scenario 2: 2 participants died
- …
- Scenario m_k: m_k participants died

For each of the resulting $(m_0 + 1) \times (m_1 + 1)$ combinations, we will calculate a contingency table and associated chi-square p value and examine which combinations are consistent with the non-imputed analysis. This will tell us how extreme the missing data assumption would need to be to provide a result that is different to the non-imputed analysis.

Subgroup analyses

A subgroup analysis will examine whether the effect of intervention is moderated by level of lesion (paraplegia or tetraplegia) or age (< 30, 30–50, > 50 years). The subgroup analysis will be conducted on the time to death outcome using a Cox model with terms for intervention, level of lesion (or age), and the intervention by level of lesion (or age) interaction.

Efficacy analysis: secondary outcomes

Between-group comparisons of secondary outcomes will be conducted using linear models, adjusting only for the stratification and baseline variables. In these models, the outcome will be a linear function of intervention and level of lesion (tetraplegia or paraplegia). For continuous outcomes, baseline scores will be included in the model to increase statistical precision and statistical power. The effect of intervention on continuous outcomes will be estimated as the adjusted mean difference and 95% confidence interval. For binary outcomes, log-binomial regression will be used. The effect of intervention on binary outcomes will be estimated as the adjusted ratio of proportions and 95% confidence interval.

Missing data handling

The efficacy analysis of secondary endpoints will use all available data. Missing data will not be imputed.

Complier average effects and survivor average effects

If there is substantial non-compliance with the intervention (fewer than 75% of planned phone contacts or home visits), the complier average causal effect of intervention on all-cause mortality at 2 years will be estimated. The number of phone contacts and the number of home visits with participants in the intervention group will be used to quantify adherence to the protocol by participants in the intervention group. It will be assumed that participants in the control group are unable to access the intervention. The complier average causal effects will be estimated using instrumental variable regression [13].

If there is a substantially different survival in the intervention and control groups (greater than 5% absolute difference in survival at 2 years), a sensitivity analysis will be conducted to determine the plausible range of survivor average causal effects on secondary outcomes using the method described by Chiba and Vanderweele [14].

Safety analysis

The safety analysis will consist of documentation of serious adverse events, deaths, hospitalisations, and events resulting in persistent or significant disability. Comprehensive safety data will be obtained from participants in the intervention group over the course of the trial because the research team will be in regular contact with

participants in the intervention group. In contrast, incomplete safety data will be obtained from participants in the control group over the course of the trial because the research team has little or no contact with participants in the control group until follow-up at 2 years. The closer monitoring of intervention group participants over the course of the trial generates a potential ascertainment bias which makes interpretation of these safety data potentially misleading. For that reason, we will not conduct formal between-group comparisons of safety data collected over the course of the trial and we do not anticipate providing details of this information in the primary trial report. Instead, the efficacy analyses will be used to provide insights into safety because the primary outcome and many of the secondary outcomes reflect adverse events.

Figures and tables

The final report will include the CONSORT flow chart (Fig. 1) and five tables (Additional file 1).

Discussion

This paper presents the statistical analysis plan for the CIVIC trial. By publishing the statistical analysis plan

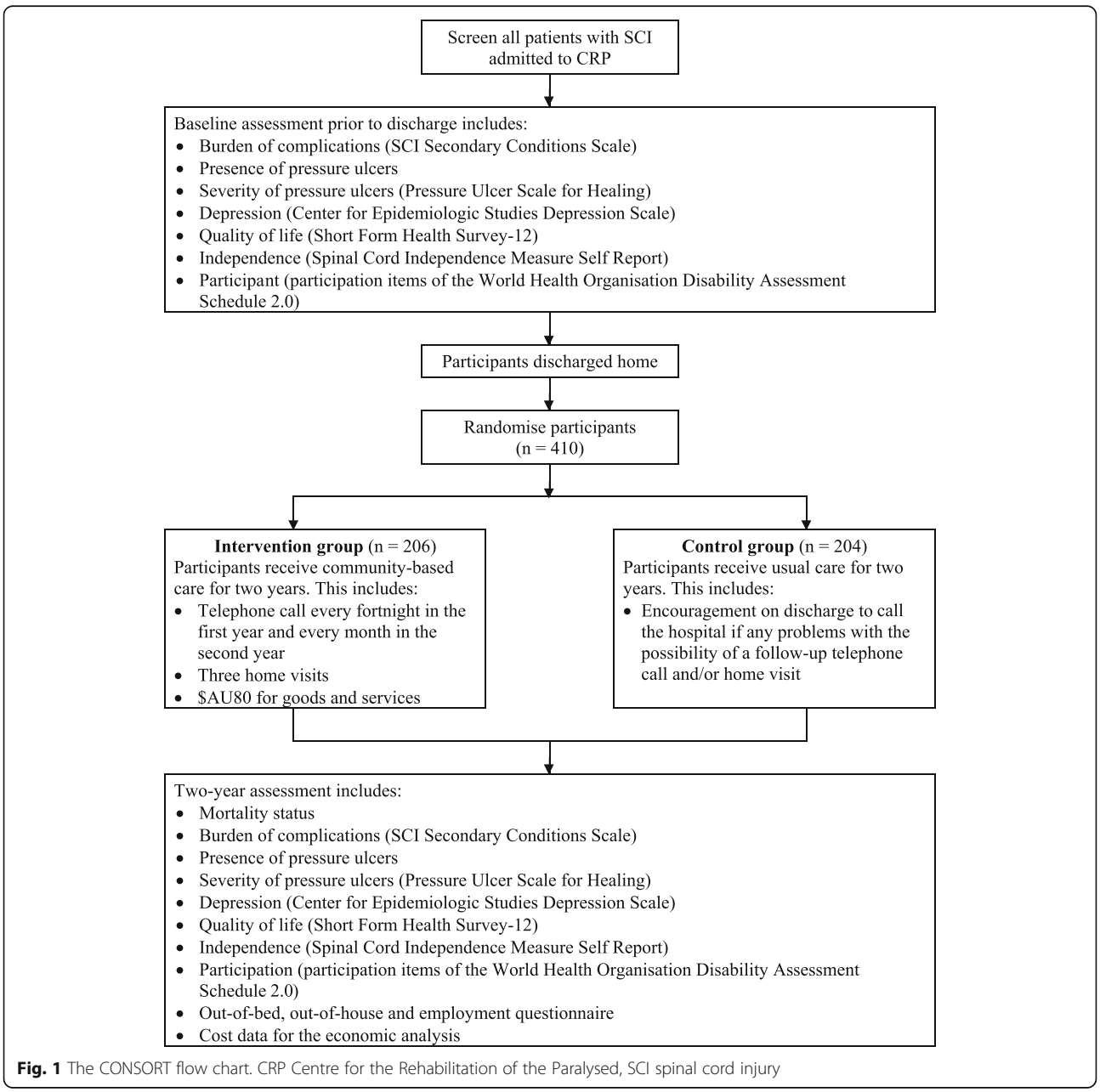

Fig. 1 The CONSORT flow chart. CRP Centre for the Rehabilitation of the Paralysed, SCI spinal cord injury

while the trial is still underway, we can subsequently demonstrate, when the trial report is produced, that the data were analysed according to a pre-specified plan. Readers of the trial report will be able to check if the trial was subject to post-hoc or data-driven analyses.

Changes from the register and published study protocols

This detailed statistical plan includes two minor changes to the statistical analysis procedures described briefly in the trial register and the published protocol. They are:

1. The register indicates that between-group comparisons of binary secondary outcomes will be conducted using logistic regression, but instead log-binomial regression will be used.
2. The published protocol indicates that multiple imputation will be used if more than 5% of data are missing for a particular analysis. Instead, efficacy analyses will be conducted on all available data without imputation. An analysis of the sensitivity of findings to missing data will be conducted using the all-cause mortality outcome.

This statistical analysis plan supersedes the information previously provided in the registry and the published protocol. The registry and the working version of the protocol will be updated to make them consistent with this statistical analysis plan.

Trial status

Key dates in the conduct of the trial are as follows:

- The trial was registered on 17 June 2015 with the Australian and New Zealand Clinical Trial Registry (https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=368756).
- The first participant was randomised on 12 July 2015.
- The last participant was randomised on 19 March 2018.
- The first participant finished the trial on 3 August 2017.
- The last participant will finish the trial in March 2020.
- The trial protocol was submitted for publication on 23 October 2015 [7].
- This statistical plan is Version 5, dated 12 April 2018.
- This statistical plan was ratified on 12 April 2018 prior to inspection of the data.

Endnotes

[1]In Stata:landemets, alpha(0.05) method(obf) t(0.5(0.5)1) matrix LANDEMETS = r(bound_alpha)local OBFalpha = LANDEMETS[2, 5]stpower logrank 0.834 0.934, power(0.8) alpha(`OBFalpha') wdprob(0.15)(Note: the landemets command is a user-written command.)

Additional file

Additional file 1: Shells for the five tables that will be included in the final report of the trial (do not include data). (DOCX 45 kb)

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Md. Akhlasur Rahman
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Stephen Jan
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Ian D. Cameron
Harvinder Singh Chhabra
Richard I. Lindley
Fin Biering-Sørensen

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Availability of data and materials

Not applicable.

Authors' contributions

RDH, LB, and QL are responsible for statistical design and analysis. MSH, LAH, RDH, IC, RL, SJB, SM, and VT were responsible for the design of the intervention and the trial. MSH, LAH, RDH, IC, RL, SJ, SM, VT, FB-S, IC, RL, and HSC secured funding. SJ is responsible for the economic analyses. MSH, MSI, VT, SM, and AR are responsible for the local site. MD is the trial coordinator. All the authors have read and approved the final manuscript.

Ethics approval and consent to participate

Ethical approval was obtained from the Ethics Review Committees of the Centre for the Rehabilitation of the Paralysed, Bangladesh (CRP-R&E-0401-126), and the University of Sydney, Australia (2015/041). Informed consent was obtained from all participants.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

Publisher's Note

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Chapter 6 Protocol for process evaluation of the CIVIC trial

Protocol for process evaluation of the CIVIC randomised controlled trial: Community-based Interventions to prevent serious complications following spinal cord injury in Bangladesh-study protocol.This study has been published in a peer-reviewed journal and is presented in its published format.

Published manuscript:

Mohammad Sohrab Hossain, Lisa A Harvey, Hueiming Liu, Md. Shofiqul Islam, Md. Akhlasur Rahman, Stephen Muldoon, Fin Biering-Sorensen, Ian D Cameron, Harvinder S Chhabra, Richard I Lindley, Stephen Jan. Protocol for process evaluation of CIVIC randomised controlled trial: Community-based InterVentions to prevent serious Complications following spinal cord injury in Bangladesh. BMJ Open 2018;8: e024226. doi:10.1136/bmjopen-2018-024226.

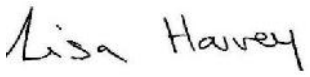
Publication statement: Statement from co-authors confirming the authorship contribution of the PhD candidate.

Mohammad Sohrab Hossain, Lisa A Harvey, Hueiming Liu, Md. Shofiqul Islam, Md. Akhlasur Rahman, Stephen Muldoon, Fin Biering-Sorensen, Ian D Cameron, Harvinder S Chhabra, Richard I Lindley, Stephen Jan. Protocol for process evaluation of CIVIC randomised controlled trial: Community-basedInterVentions to prevent serious Complications following spinal cord injury in Bangladesh. BMJ Open 2018;8: e024226. doi:10.1136/bmjopen-2018-024226.

We confirm that Mohammad Sohrab Hossain has made the following contributions for this paper:

- Conception and design of the protocol including literature search
- Analysis and interpretation of the findings
- Writing the manuscript, critical appraisal of content and response to reviewers

Authors' names and signatures:

Name	Signature
Lisa A Harvey	
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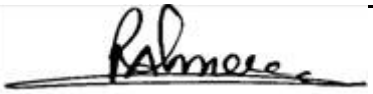
Md. Akhlasur Rahman	
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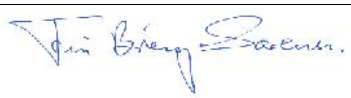
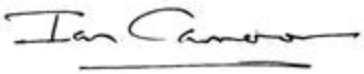
Fin Biering-Sorensen	
Ian D Cameron	
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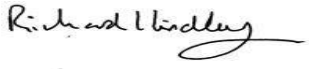
Richard L Lindley	
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Protocol for process evaluation of CIVIC randomised controlled trial: Community-based InterVentions to prevent serIous Complications following spinal cord injury in Bangladesh

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ABSTRACT

Introduction People with spinal cord injuries in low-income and middle-income countries are highly vulnerable to life-threatening complications in the period immediately after discharge from hospital. We are conducting a randomised controlled trial in Bangladesh to determine whether all-cause mortality at 2 years can be reduced if health professionals regularly ring and visit participants in their homes following discharge. We will conduct a process evaluation alongside the trial to explain the trial results and determine the feasibility of scaling this intervention up in low-income and middle-income countries if it is found to be effective.

Methods and analysis Our process evaluation is based on the Realist and Reach, Effectiveness, Adoption, Implementation and Maintenance frameworks. We will use a mixed methods approach that uses both qualitative and quantitative data. For example, we will audit a sample of telephone interactions between intervention participants and the healthcare professionals, and we will conduct semistructured interviews with people reflective of various interest groups. Quantitative data will also be collected to determine the number and length of interactions between the healthcare professionals and participants, the types of issues identified during each interaction and the nature of the support and advice provided by the healthcare professionals. All quantitative and qualitative data will be analysed iteratively before the final analysis of the trial results. These data will then be triangulated with the final results of the primary outcome.

Ethics and dissemination Ethics approval was obtained from the institutional ethics committee at the site in Bangladesh and from the University of Sydney, Australia. The study will be conducted in compliance with all stipulations of its protocol, the conditions of ethics committee approval and the relevant regulatory bodies. The results of the trial will be disseminated through publications in peer-reviewed scientific journals and presentations at scientific conferences.

Trial registration number ACTRN12615000630516.

Strengths and limitations of this study

- The process evaluation involves mixed methods and draws together data from many different sources to help explain the trial results and determine the feasibility of scaling this intervention up in low-income and middle-income countries.
- The Community-based InterVentions to prevent serIous Complications following spinal cord injury in Bangladesh (CIVIC) trial will be the first large randomised controlled trial to look at the effectiveness of any type of community-base support programme for people with spinal cord injuries in a low-income or middle-income country.
- The process evaluation relies on staff involved in the trial to collect some of the data. This may introduce bias.
- The process evaluation does not collect data from the early stages of the trial.

INTRODUCTION

There are no accurate data on the incidence of spinal cord injuries (SCI) in low-income countries such as Bangladesh but most working in the area believe that it could be as high as 70 per million.[1 2] That is, three to four times that of high-income countries.[3] Similarly, there are few accurate data about survival following SCI in these countries.[4–7] However, our own estimates from one specialised service in Bangladesh indicate that 19% of people with SCI who are wheelchair-dependent and survive until discharge, die within 2 years.[8] Most are young males dying from complications such as sepsis due to pressure ulcers.[8–11] There is therefore a pressing need to find sustainable ways of supporting people

with SCI in the community following discharge, particularly those at high risk of complications.

The Community-based InterVentions to prevent serIous Complications following spinal cord injury in Bangladesh (CIVIC) trial was designed to test the effectiveness of an inexpensive and sustainable model of community-based care that could be rolled out in Bangladesh and other low-income countries to support people with SCI following discharge. The model of care was developed over a number of years and over the course of a preliminary pilot study.[12] It involves assigning healthcare professionals for 2 years to people with SCI as they are discharged from hospital. The healthcare professionals act like case managers and are in regular telephone contact with participants, and responsible for monitoring for complications, providing advice and support, and being a familiar point of contact for participants and their families. The assigned healthcare professionals also visit participants in their homes and provide participants with a small amount of financial assistance ($AU80). The healthcare professionals are thus responsible for proactively supporting participants and their families on discharge and providing them with regular support and advice, as well as monitoring for early signs of complications.

The primary outcome of CIVIC trial is all-cause mortality at 2 years. Recruitment to the study commenced in July 2015 and finished in March 2018 with the final follow-up assessment due in March 2020. The process evaluation described in this paper will help explain the results of the trial and determine the feasibility of scaling up this intervention in Bangladesh and other low-income and middle-income countries if it is found to be effective.

Aim

The aims of the process evaluation are to:

1. Explain CIVIC trial results and specifically, to determine:
   - Whether the intervention was delivered as intended.
   - Whether the control was delivered as intended.
   - The types of issues typically identified during each interaction between intervention participants and healthcare professionals.
   - The nature of the support and advice provided by the healthcare professionals to the intervention participants.
   - Participants' and healthcare professionals' perspectives on how, why and for whom the intervention did or did not work.
2. Determine the feasibility of scaling the intervention up in Bangladesh and other low-income and middle-income countries if it is found to be effective and specifically, to determine:
   - The possible barriers and facilitators to scaling the intervention up in the future.
   - Whether people with SCI would value the intervention.
   - Whether healthcare service providers could employ and retain staff to provide the intervention.
   - Whether the results are generalisable to other patients, healthcare service providers and countries.

METHODS AND ANALYSES

Summary of CIVIC trial

An investigator-initiated pragmatic randomised controlled trial is being undertaken. The trial was prospectively registered with the Australia New Zealand Clinical Trials Registry and the trial protocol has been published.[13] In brief, 410 people with recent SCI who are wheelchair dependent and about to be discharged home from the Centre for the Rehabilitation of the Paralysed in Bangladesh are randomised to either an intervention or control group (see figure 1). Participants in the intervention group receive our model of community-based care for2 years in which they are assigned a healthcare professional who rings them every 2weeks in the first year and every month in the second year, and visits them in their homes on three occasions over the 2 years. At each point of contact, the healthcare professional screens participants for early signs of complications, and provides them and their families with advice and support. In contrast, participants in the control group receive the care that is currently provided by the Centre for the Rehabilitation of the Paralysed. That is, at discharge participants are encouraged to ring the hospital if they develop any problems, and some are rung or visited on one occasion by hospital staff as part of the hospital's limited follow-up service.

The primary outcome is all-cause mortality at 2 years determined by blinded assessors interviewing next of kin (Bangladesh does not have a death registry). There are also a number of secondary outcomes including complications, depression, independence, quality of life and ability to participate in community activities.

The trial is powered to have a 80% probability of detecting an increase in survival from 83%[8] to 93% at 2 years with a two-sided log-rank test, uniform follow-up time of 2 years, loss to follow-up in both groups of 15% at 2 years and an alpha of 0.05. A trial-based economic evaluation will be conducted based on differences observed between groups in costs, overall survival and quality-adjusted survival at 2 years. This will enable an estimate of an incremental cost per quality adjusted life year of the intervention over standard care.

The theoretical framework for our process evaluation

Figure 2 outlines the framework of our process evaluation as recommended by the Medical Research Council's guidance on process evaluations of complex interventions.[14] It provides a summary of the key questions and the proposed causal pathways between CIVIC trial intervention and outcomes within the context of the ultimate aim of the trial and intervention, namely to reduce complications and mortality in people with SCI after discharge from hospital.

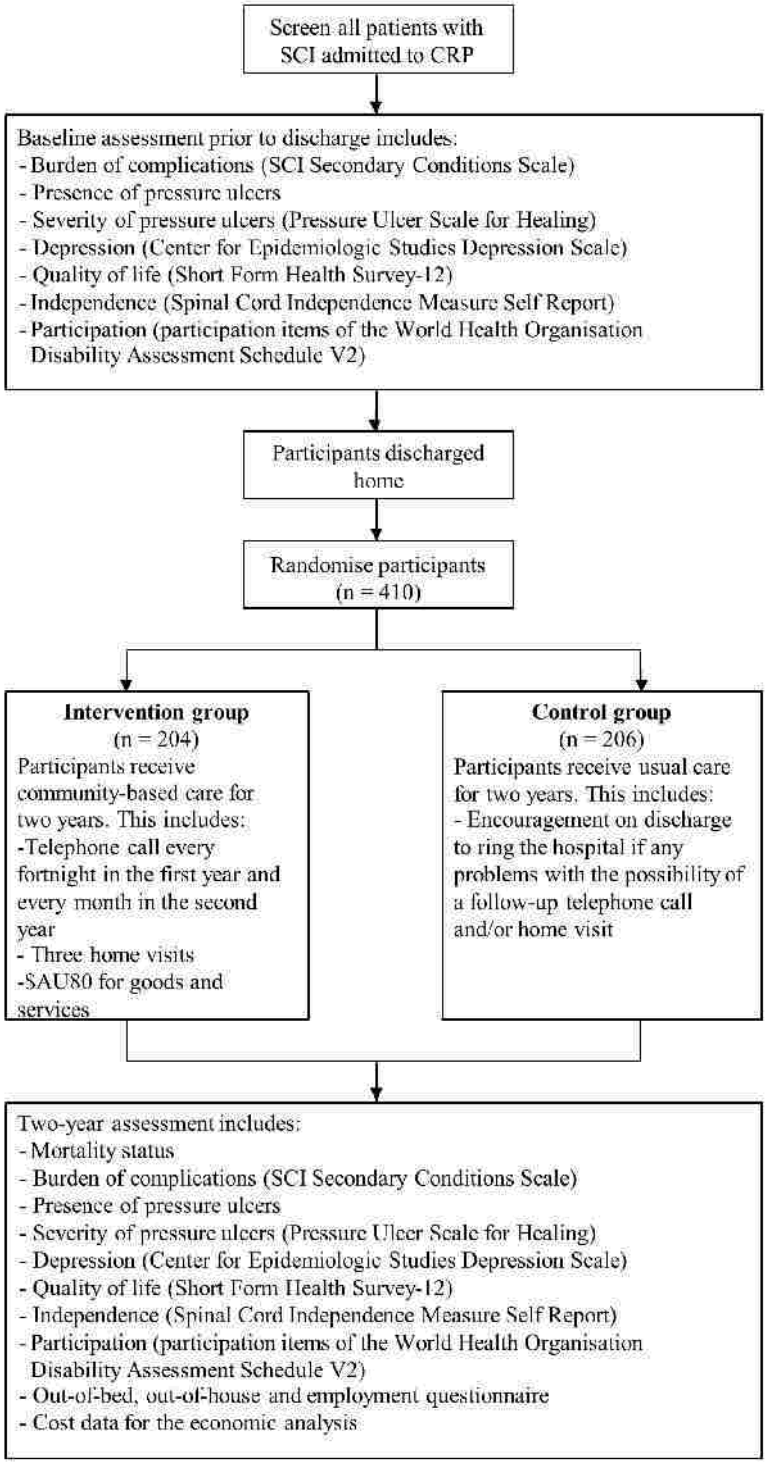

Figure 1 The CIVIC trial flow chart. CIVIC, Community-based InterVentions to prevent serIous Complications following spinal cord injury in Bangladesh; CRP, Centre for the Rehabilitation of the Paralysed; SCI, spinal cord injuries.

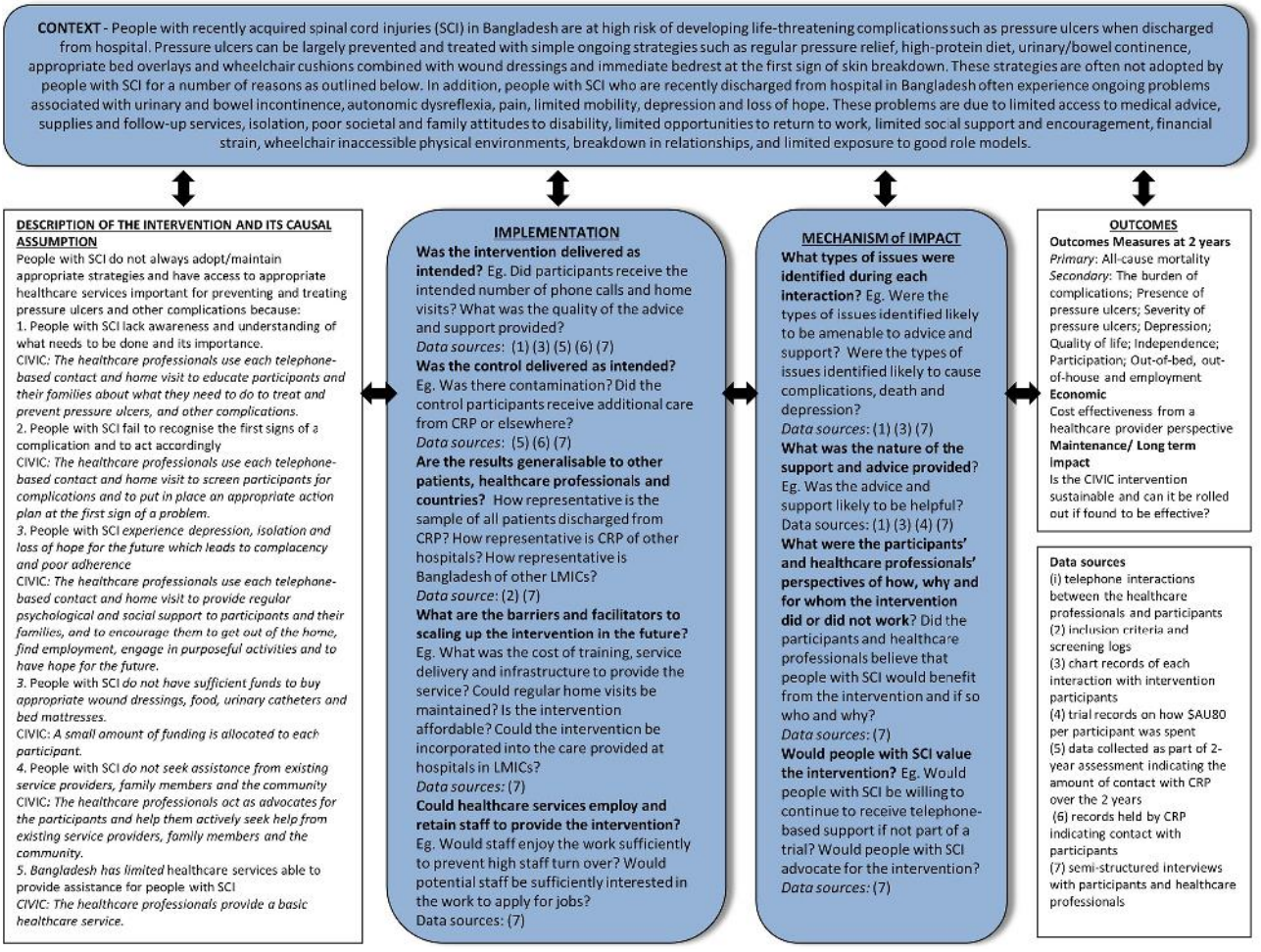

Figure 2 The process evaluation framework for the CIVIC trial. The middle blue boxes (labelled Context, Implementation and Mechanisms of Impact) include the key components of the process evaluation including exploration of the contextual factors, implementation of the trial and ways in which intervention may work. The two white boxes indicate the link between the components of the intervention and the trial outcomes. The Reach, Effectiveness, Adoption, Implementation and Maintenance and Realist frameworks guide the questions that fit within the key components of the process evaluation. The components are based on assumptions and hypotheses about how CIVIC intervention may have its effect on the primary and secondary outcomes as summarised within the two white boxes. CIVIC, Community-based InterVentions to prevent serlous Complications following spinal cord injury in Bangladesh trial; CRP, Centre for the Rehabilitation of the Paralysed; LMIC, low-income and middle-income countries; SCI, spinal cord injury.

Our process evaluation is based on the Realist[15] and Reach, Effectiveness, Adoption, Implementation and Maintenance (RE-AIM)[16] frameworks. The Realist framework is a social science method of examining the relationships between the context, mechanisms and outcomes of trials involving complex interventions to better explain the possible causal pathways through which the different components of the intervention might work. It includes consideration of whom the intervention is most likely to work for and within what context along with consideration of which aspects of the intervention are most important and for what reasons. Consideration and exploration of these factors is believed to ultimately increase the uptake of research results into clinical practice.

The RE-AIM framework[16] (reach, effectiveness, adoption, implementation and maintenance) uses qualitative and quantitative data to develop the intervention, and to then evaluate and disseminate trial findings. It covers five domains according to its acronym, namely: the *reach* of the intervention which can in part be examined by looking at those included and excluded from the trial, the *effectiveness* of the intervention which is reflected in the trial outcomes, the likely *adoption* of the intervention which can be determined by looking at how representative the site and country is of other settings, the *implementation* of the intervention as part of the trial which includes aspects of trial fidelity and cost containment and the *maintenance* of the intervention after the trial ceases. Not all aspects of the RE-AIM framework are relevant to this process evaluation but are being broadly used to guide the trial and process evaluation.

Data collection and analyses

We will use a mixed methods approach that captures both qualitative and quantitative data to address the aims of our process evaluation. All quantitative and qualitative

Table 1 The data-collection methods that will be used to address each aim

Aims	Data-collection method 1	2	3	4	5	6	7
Explain the trial results							
Whether the intervention was delivered as intended	X		X		X	X	X
Whether the control was delivered as intended					X	X	X
The types of issues typically identified during each interaction between intervention participants and healthcare professionals	X		X				X
The nature of the support and advice provided by the healthcare professionals to the intervention participants	X		X	X			X
Participants' and healthcare professionals' perspectives on how, why and for whom the interventions did or did not work							X
Determine the feasibility of scaling the intervention up in Bangladesh and other low-income and middle-income countries							
The possible barriers and facilitators to scaling the intervention up in the future							X
Whether people with spinal cord injuries would value this intervention							X
Whether healthcare service providers could employ and retain staff to provide the intervention							X
Are the results generalisable to other patients, healthcare service providers and countries		X					X

Legend for data-collection methods:
1. Analysis of a sample of telephone interactions between healthcare professionals responsible for providing the intervention and intervention participants.
2. Inclusion criteria and screening logs.
3. Chart audit of data collected over the trial that captures the number, length and nature of interactions between healthcare professionals and participants.
4. Audits of trial records detailing how and to whom each intervention participant's allocated $AU80 was spent.
5. Chart audit of data collected as part of 2-year assessment indicating the amount of contact control and intervention participants had with the Centre for the Rehabilitation of the Paralysed over the 2 years.
6. Record audit of the Social Welfare Department and Community Based Rehabilitation Unit at the Centre for the Rehabilitation of the Paralysed indicating contact with control and intervention participants.
7. Semistructured interviews with participants and healthcare professionals.

data will be analysed iteratively before the final analyses of the trial results. These data will then be triangulated with the final results of the primary outcome. The type of data that will be collected to address each aim of the process evaluation is outlined in figure 2 and table 1.

The details are as follows:

Analysis of a sample of telephone interactions between the healthcare professionals responsible for providing the intervention and the intervention participants

The purpose of these analyses will be to explore:

- Whether the intervention was delivered as intended.
- The types of issues typically identified during each interaction between the healthcare professionals and intervention participants.
- The nature of the support and advice provided by the healthcare professionals to the intervention participants.

Recordings will be taken of 20 telephone interactions between the intervention participants and the different healthcare professionals responsible for providing the intervention. Only participants who are currently in the trial at the time of data collection will be sampled. The selection of the telephone interactions will be made prior to recording and selected to ensure maximal representation of the different types of participants including: those living in rural locations versus living in urban locations; those with paraplegia versus tetraplegia; and those with minimal problems since discharge versus multiple problems since discharge. The telephone interactions will be in Bangla and will be recorded and then translated ad verbatim into English.

The recordings will be analysed using a predesigned checklist to determine how much time is spent talking directly to participants as opposed to friends or family members and how much time is spent screening for complications, providing advice, providing psychological support and engaging in social conversation. In addition, a tally will be made of the types of complications and issues that are discussed.

Audit of the inclusion criteria and screening logs

The purpose of these analyses will be to determine:

- Whether the results are generalisable to other patients, healthcare service providers and countries.

The detailed screening log kept by trial staff of all patients with SCI admitted to the Centre for the Rehabilitation of the Paralysed who are subsequently

discharged home over the duration of the study will be examined to determine the difference between the number of patients discharged home and the number of patients ultimately randomised to the trial. These data will provide some insight into the generalisability of the results.

Chart audit of data collected over the trial that captures the number, length and nature of interactions between the healthcare professionals and participants

The purpose of these analyses will be to determine:

- Whether the intervention was delivered as intended.
- The types of issues typically identified during each interaction between intervention participants and healthcare professionals.
- The nature of the support and advice provided by the healthcare professionals to the intervention participants.

The charts kept by the healthcare professionals responsible for providing the intervention will be audited. These charts are purpose-designed forms used to record the details of every interaction with intervention participants over the course of the trial. The forms capture the type of each interaction (telephone or home visit), the length of each interaction as well as the issues discussed, key problems and advice provided during each interaction. We will use these data to determine whether intervention participants received a phone call every fortnight in the first year and every month in the second year, the median (IQR) length of each interaction and the types of complications and issues that were discussed and the type of advice provided.

Audits of trial records detailing how and to whom each intervention participants' allocated $AU80 was spent: The purpose of these analyses will be to determine:

- The nature of the support and advice provided by the healthcare professionals.

The intervention involves the allocation of a small amount of money for each intervention participant. This money is spent according to individual needs but overseen by the healthcare professional allocated to the participant. Detailed records are kept on how this money is spent. We will audit these records to summarise the types of goods and services that are purchased and the amount of money provided to intervention participants. These data will help understand how the intervention may have its effect and the economic implications of scaling this intervention up in the future.

Chart audit of data collected as part of the 2-year assessments indicating the amount of contact control and intervention participants had with non-trial staff from the Centre for the Rehabilitation of the Paralysed since discharge

The purpose of these analyses will be to determine whether:

- The control was delivered as intended.
- The intervention was delivered as intended.

At the time of protocol development, usual care was minimal. Most patients were discharged home with no formal follow-up from the Centre for the Rehabilitation of the Paralysed although sometimes patients were rung or visited on one occasion. If the results of the trial are negative then it will be important to explore whether this level of care increased since the commencement of the trial leading to contamination, and if so, whether control participants were receiving more contact from hospital staff as part of usual care than intervention participants. We will do this by tallying the number of times control and intervention participants had contact with non-trial staff from the Centre for the Rehabilitation of the Paralysed over the course of the study. These data are being collected as part of the 2-year assessments. Participants are asked how many times they have had contact with trial staff from the Centre for the Rehabilitation of the Paralysed in the preceding 2 years since discharge. We will tally these data.

Record audit of the Social Welfare Department and Community-Based Rehabilitation Unit at the Centre for the Rehabilitation of the Paralysed

The purpose of these analyses will be to determine whether:

- The control was delivered as intended.
- The intervention was delivered as intended.

We will use a second source of data to determine the amount of contact control and intervention participants had with non-trial staff from the Centre for the Rehabilitation of the Paralysed over the course of the study as part of usual care, and specifically contact with staff from the Social Welfare Department and Community Based Rehabilitation Unit at the Centre for the Rehabilitation of the Paralysed. These staff ring approximately 30 patients per month from a list of patients discharged over the last 30 years. Staff do not know which patients are part of the trial and whether those involved are control or intervention participants. The list of patients that are rung are being collected and will be used to determine how many control and intervention participants were contacted by staff not involved in CIVIC trial as part of usual care. We will also summarise any advice or follow-up care provided.

Semistructured interviews with participants and healthcare professionals

The purpose of these interviews will be to explore:

- Whether the intervention was delivered as intended.
- Whether the control was delivered as intended.
- The types of issues typically identified during each interaction between intervention participants and healthcare professionals.
- The nature of the support and advice provided by the healthcare professionals to the intervention participants.
- Participants' and healthcare professionals' perspectives on how, why and for whom the interventions did or did not work.

- The possible barriers and facilitators to scaling the intervention up in the future.
- Whether people with SCI would value this intervention.
- Whether healthcare service providers could employ and retain staff to provide the intervention.
- Whether the results are generalisable to other patients, healthcare service providers and countries.

The interviews will be conducted by the first author (SH). He lives in Bangladesh, is fluent in Bangla and English, is a principal investigator and has worked at the Centre for the Rehabilitation of the Paralysed for over 15 years (initially as a clinical physiotherapist and then as the head of medical services). All interviews will be conducted and recorded in Bangla, and then translated ad verbatim into English (unless the healthcare professional and participant are fluent in English). The interviews will follow an interview guide which outlines broad topics to be discussed. The topics address the various purposes of the process evaluation (see online supplementary appendix 1 for types of questions that will be asked). The interviews will be conducted on a one-to-one basis and are expected to take 1–2 hours each.

Purposeful sampling will be used to select 20 participants and 14 healthcare professionals. The participants will not be the same as those used to capture the telephone interactions. Instead, they will be a mix of control and intervention participants who are either currently on the trial or have recently completed the trial, and will be selected to ensure best possible representation from a combination of the various interest groups including: living in a rural location versus living in an urban location, paraplegia versus tetraplegia, minimal problems since discharge versus multiple problems since discharge. The 14 healthcare professionals will include four staff members working on CIVIC trial who are either responsible for delivering the intervention or overall management of the trial. The remaining 10 healthcare professionals will be people not directly involved in CIVIC trial but with extensive experience or understanding of the management of people with SCI in Bangladesh. It will include people working at the Centre for the Rehabilitation of the Paralysed and working in rehabilitation in the community; and people who are in daily contact with people with SCI as well as those in managerial roles likely to have insight into the barriers and facilitators of scaling the intervention up in the future.

Patient and public involvement

People with SCI in Bangladesh were not directly involved in prioritising the research question underpinning CIVIC trial, although it is perhaps reasonable to assume that an intervention which aims to reduce mortality would be considered a priority for this group of people. As part of the process evaluation, participants in the intervention group will be asked about their experiences and perceptions of the intervention, and in particular whether they found the regular contact with healthcare professionals burdensome. We will ensure that participants of the trial are informed about the results. We will achieve this by sending them a one-page summary of the main findings in Bangla on completion of the trial.

ETHICS AND DISSEMINATION

Ethics

The study is being conducted in compliance with all stipulations of the study protocol, the conditions of ethics committee approval, the National Health and Medical Research Council National Statement on Ethical Conduct in Human Research (2007),[17] the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95)[18] and the Bangladesh Guidance on Clinical Trial Inspection (2011).[19]

Ethic approval will be sought for all protocol modifications. Any changes to the protocol will be updated on the registry.

Dissemination

CIVIC trial will provide unbiased and precise estimates of the effectiveness and cost-effectiveness of an inexpensive and sustainable model of community-based care for people with SCI in Bangladesh. Evidence of effectiveness and cost-effectiveness will have widespread implications for provision of health services for people with SCI and other conditions that cause serious disability in low-income and middle-income countries.

Process evaluations conducted alongside trials involving complex interventions such as that provided in CIVIC are widely advocated because the causal links between the different components of the intervention and outcomes of the trial are not always clear. The intervention provided as part of CIVIC is a complex community-based rehabilitation intervention that is based on similar services provided in high-income countries and studies which have advocated the benefits of telephone-based support for people with SCI.[20 21] The intervention is complex because it involves repeated interactions between healthcare professionals and intervention participants over a 2-year period as well as the provision of a small amount of financial support. Details about the intervention have been described in our trial protocol according to the Template for Intervention Description and Replication checklist.[22] Importantly, attention has been directed at ensuring the intervention is delivered as intended. For this reason, trial staff are regularly trained and provided with standard forms and screening logs which are completed each time they have contact with an intervention participant. However, it is not possible nor is it desirable to ensure that all interactions between trial staff and intervention participants are exactly the same. The trial is pragmatic and hence trial staff are expected to individualise their interactions with intervention participants according to their many diverse needs. The nature of each interaction will also depend on the personalities of both the trial staff and the intervention participants. Some interactions may be largely social and the trial staff may not obviously provide

any advice or support. However, regular contact with a concerned and supportive healthcare professional may be important for people who otherwise have very little contact with healthcare professionals and may be socially isolated. The skills of staff may also differ in keeping with the pragmatic nature of the trial and reflecting the realities of how this intervention would be provided in the future, if successful. Some staff may be very skilled at providing advice and support while others may not be as skilled. It is important to explore the nature of the interactions to better understand how the skill of staff may or may not influence outcomes and how the intervention may or may not work. As such, our process evaluation will look at some of these key contextual factors that both contribute to and hinder the potential benefit of the intervention and that are important for understanding different aspects of the intervention.

The intervention includes the allocation of a small amount of money for each participant to spend on services and goods such as dressings for pressure ulcers, catheters for bladder management, mattresses for beds and transport for medical attention. It will be important to determine how this money was spent as part of the process evaluation and whether it was considered an essential and important aspect of the intervention. These data will also provide insight into the economic implications of living with SCI in a country like Bangladesh and the role poverty plays in complications, mortality, depression and quality of life. Answers to these questions will help us better understand whether financial assistance is an essential aspect of the intervention and needs to be included when scaling up the intervention.

An important barrier to scaling the intervention up in the future if it is found to be effective will be cost. While a formal economic analysis from the healthcare provider perspective will be performed as part of the trial, the results of this process evaluation will also provide insight into economic barriers to scaling up of the intervention. So, interviews with healthcare professionals involved in management will explore their perspectives on the financial constraints and implications of rolling out the intervention. We will combine this information with the results of the formal economic analysis to make recommendations on the overall financial implications of scaling up the intervention across Bangladesh and other low-income and middle-income countries. We have done similar for a trial designed to determine the effectiveness of family-led rehabilitation following stroke in India (ATTEND trial).[23 24] The process evaluation that formed part of the ATTEND trial has guided the process evaluation for CIVIC trial.

In all, our process evaluation will be an important aspect of CIVIC trial. It will explore facilitators and barriers to rolling this intervention out in the future if it is found to be effective. Regardless of CIVIC trial results, our process evaluation will help guide future research in this much-neglected area.

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Contributors MSH, LAH, IDC, RLL, SJ and SM were responsible for the design of the intervention and the trial. MSH, LAH, IDC, RLL, SJ, SM FB-S and HSC secured funding. SJ was responsible for the economic analyses. SJ, HL, MSH and LAH were responsible for the design of the process evaluation. MSH and HL were responsible for collection of the qualitative data. MSI, SM and MAR were responsible for the local site. All authors have read and approved the final manuscript.

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Competing interests None declared.

Patient consent Not required.

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Provenance and peer review Not commissioned; peer reviewed for ethical and funding approval prior to submission.

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Chapter 7 Poverty following spinal cord injury: analysis of baseline data from the CIVIC trial

A cross-sectional study to determine levels of poverty from the baseline data of the CIVIC randomised controlled trial: Community-based interventions to prevent serious complications following spinal cord injury in Bangladesh.This study has been published in a peer-reviewed journal and is presented in its published format.

Published manuscript:

Mohammad Sohrab Hossain, Lisa A. Harvey, Md. Shofiqul Islam, Md. Akhlasur Rahman, Hueiming Liu, Robert D. Herberton behalf of the CIVIC Trial Collaboration. Loss of work-related income impoverishes people with spinal cord injury and theirfamilies in Bangladesh. Spinal Cord (2020) 58:423–429.

Conference proceedings:

This study has been presented at three conferences. It appears in the conference proceedings as:

- Hossain MS et al. (2018). Spinal cord injuries in low- and middle-income countries throw families into poverty: a cross-sectional study on a consecutive series of patients about to be discharged from a hospital in Bangladesh. *Asian Spinal Cord Network*, Yangon, Myanmar.
- Hossain MS, MS Islam, MA Rahman, RD Herbert, S Muldoon, V Taylor, LA Harvey on behalf of the CIVIC Collaboration (2018). Spinal cord injuries in low- and middle-income countries throw families into poverty: a cross-sectional study on a

consecutive series of patients about to be discharged from a hospital in Bangladesh. *International Spinal Cord Society conference*, Sydney Australia.

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We confirm that Mohammad Sohrab Hossain has made the following contributions for this paper:

- Conception and design of the research including literature search
- Collection of data
- Analysis and interpretation of the findings
- Writing the manuscript, critical appraisal of content and response to reviewers

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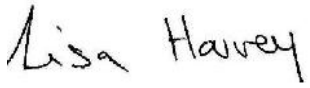
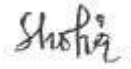
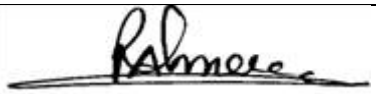
Lisa A Harvey	
Md. Shofiqul Islam	
Md. Akhlasur Rahman	
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ARTICLE

Loss of work-related income impoverishes people with SCI and their families in Bangladesh

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Abstract

Study design Cross-sectional study.

Objectives To determine the degree of impoverishment of people with spinal cord injury (SCI) and their families in Bangladesh caused by loss of work-related income following injury.

Setting Spinal cord injury centre, Bangladesh.

Methods A total of 410 wheelchair-dependent people with recent SCI about to be discharged from a hospital in Bangladesh were interviewed to determine the size of their families, their incomes from paid work prior to injury and the incomes of their family members. These data were used to calculate income per family unit and per family member prior to and immediately after injury.

Results Ninety percent of the participants were men, 98% were from rural areas of Bangladesh and 58% were manual labours prior to injury. Median (interquartile range, IQR) family size was 5 (4–6) people. Prior to injury, 74% of participants were the main income earners for their families and 50% provided the only source of income for their families. Participants' median (IQR) monthly income prior to injury was US$106 (US$60–US$180) per person and family members' income was US$30 (US$19–US$48) per person. After injury, the median income (IQR) of each family member dropped to US$0 (US $0–US$18) placing 91% of families below the extreme poverty line of US$37.50 per person per month (equivalent to US $1.25 per day).

Conclusion In Bangladesh, SCI have profound financial implications for individuals and their families and causes extreme poverty. This is because those most often injured are young and the main income earners for their families.

Introduction

In Bangladesh, spinal cord injuries (SCI) are commonly due to work-related accidents in young manual labourers [1–5], often with low socioeconomic backgrounds [6–8]. A similar pattern is seen across other low- and middle-income countries (LMIC) [9–12]. SCI causes hardship for those who are injured and often also for the families who are financially dependent on them [3, 13–15]. The loss of income and additional medical and ongoing costs associated with the injury place a large financial strain on families [16, 17]. Not surprisingly, therefore, SCI in Bangladesh and other LMIC often throws families into extreme poverty [18–20].

We previously quantified the financial implications of SCI on individuals and their families in Bangladesh [3]. For that purpose, we interviewed 283 of the 350 people with an SCI who had been discharged from a large

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hospital in Bangladesh in 2011, 2 years following discharge (55 of the 350 had died and 11 were lost to follow-up). Interviewees were asked about family income and employment status prior to injury and at the time of interview. We found that the median (interquartile range, IQR) income of each family member living with a person with SCI was US$20 (US$13–US$39) per person per month. This is less than the extreme poverty line in Bangladesh (US$37.50 per person per month or US$1.25 per person per day) [21]. These data probably underestimate the financial distress experienced by many people with SCI and their families because the cohort included 115 people who were walking and hence less disabled than their wheelchair-dependent counterparts.

In a 5-year follow-up of the same cohort we collected and analysed additional data according to walking status at discharge. The median (IQR) income of those who were wheelchair dependent at discharge and still alive at 5 years ($n = 141$) was US$0 (US$0–US$65); much less than pre-injury incomes of US$65 (US$39–US$104). Seventy-five percent were living below the poverty line (US$57 per month or US$1.90 per day) and only 35% were in full-time employment 5 years after discharge. The limitation of these data is that we did not calculate income per family member, and the pre-injury data may not have been accurate because we asked participants to remember their incomes many years earlier. In addition, we did not have data about participants' and their families' financial situation during the period after injury when the person was hospitalised. The current study was designed to overcome these limitations and provide more accurate data on the financial implications of SCI on those injured and their families in Bangladesh. Specifically, the aim was to determine the degree of impoverishment of people with SCI and their families caused by the loss of work-related income following SCI in Bangladesh.

The data from this study reflects those with recent SCI admitted to the Centre for the Rehabilitation of the Paralysed (CRP) who were wheelchair dependent on discharge. The CRP is a large rehabilitation centre in Bangladesh that admits more than 400 people with recent SCI from anywhere in Bangladesh each year (see [3] for the details about the types of people typically admitted each year to CRP). People with SCI are referred to CRP by government and non-government hospitals, although some patients are also self-referred. Those with recent SCI are given priority admission over people seeking readmission for the management of pressure ulcers or other problems that develop after discharge from CRP. The CRP provides treatment, and multi-disciplinary comprehensive rehabilitation free of charge unless the patient has some capacity to contribute to the cost. It is the only rehabilitation facility specifically for people with SCI in Bangladesh and is recognised as one of the biggest centres of its kind in Asia.

Method

This study is part of an ongoing randomised clinical trial. The trial, known as the CIVIC trial, is due for completion in February 2020. It will determine the effect of community-based care compared with usual care on 2-year survival [22]. In the current paper we present an analysis of some descriptive data collected prior to randomisation. The trial was registered with Australian New Zealand Clinical Trials Registry (ACTRN12615000630516) and Universal Trial Number (U1111-1171-1876). The institutional and governmental regulations concerning the ethical use of human volunteers were followed.

Participants

Five hundred and nine people who were about to be discharged from CRP in Dhaka, Bangladesh, were screened between July 2015 and March 2018 for inclusion. Those who met the inclusion criteria and provided consent were recruited to the CIVIC trial. Participants were eligible if they were more than 16 years of age, had sustained a traumatic or nontraumatic SCI within the last 2 years and required a wheelchair daily for mobility. Potential participants were excluded if they were planning to move to another country or were being transferred to another hospital for medical care. Sixty-six people did not meet the inclusion criteria, and 33 were not randomised because either they declined to participate in the trial ($n = 24$) or were discharged unexpectedly ($n = 9$). Ultimately, 410 people were randomised to groups and therefore participated in the study.

Data collection

Data were collected in face-to-face interviews conducted prior to randomisation and discharge using standardised forms. Participants were asked in Bangla about the number of family members (adults and children) living with them as a family unit. We did not define the age of a child but most in Bangladesh assume that a child is a person aged less than 14 years. Participants were asked to identify the main income earner for the family. They were also asked about the employment status and income of all family members. Financial data were recorded in local currency (BDT) and subsequently converted to United States Dollar (US$) using the conversion rate at www.xe.com (accessed on 15th April 2019). Data were also collected on participants' places of

residence (rural versus urban), type of work prior to injury and literacy levels to gauge socioeconomic backgrounds.

Data analysis

The total income for each family was divided by the number of adults and children in the family to derive income per family member. Families were then defined as living below the poverty line or extreme poverty line on the basis of the average income per family member. The poverty line was defined as US$57 per person per month (~US$1.90 per person per day) and the extreme poverty line was defined as US$37.50 per person per month (~US$1.25 per person per day) as per the definitions of the United Nations and World Bank [21, 23–25].

The same calculations were repeated but with the income of the person with SCI removed to determine the average income for each adult and child within a family after loss of income. These later calculations assumed that the person with SCI had no income once injured and while in hospital, and that there was no change in the employment status of other family members since injury.

Results

Participants' characteristics

The characteristics of participants and their families as well as their work status are shown in Tables 1 and 2. The median (IQR) age of participants was 33 years (25–43), 90% were male, 57% had paraplegia, 43% had tetraplegia, 69% were married and 71% had American Spinal Injuries Association (ASIA) Impairment Scale A lesions. In addition, 98% were from rural areas of Bangladesh and 65% had no or limited ability to read. The median (IQR) size of each family (including the person with SCI) was 5 (4–6) individuals with a median (IQR) 2 (1–3) adults and 2 (1–2) children per family. We did not ask participants to specify their relationship with other adults in the household but they could have been spouses, parents, siblings or children.

Income

Prior to injury, 82% of participants were in full-time employment. Most participants (58%) were manual labourers or tradespersons (17%) prior to injury, and only nine participants (3%) had professional jobs. The others were either office workers, business workers or shopkeepers. Seventy-four percent were the main income earners for their families. In 50% of families, no other person worked. The incomes of participants and their family members before and after SCI are shown in Table 3. The monthly median (IQR) income of each family member prior to injury was US$30 (US$19–US$48) per person. This was sufficient to keep 33% of family members above the extreme poverty line. After injury, the monthly median (IQR) income of each family member was US$0 (US$0–US $18) per family member. This was sufficient to keep 9% of

Table 1 Characteristics of participants

Characteristics	Total
Participants, (*n*)	410
Gender, *n* (%)	
Male	369 (90%)
Female	41 (10%)
Age (years), median (IQR)	33 (25–43)
Time since injury (months), median (IQR)	6 (5–8)
Time in CRP (months), median (IQR)	4 (4–6)
Marital Status, *n* (%)	
Married	284 (69%)
Not married	107 (26%)
Separated/divorced	15 (4%)
Widowed	4 (1%)
Geographic location*, *n* (%)	
Dhaka	126 (30%)
Rajshahi	43 (11%)
Chittagong	74 (18%)
Sylhet	19 (5%)
Khulna	62 (15%)
Barisal	36 (9%)
Rangpur	17 (4%)
Mymensingh	33 (8%)
Residency before injury, *n* (%)	
Rural	400 (98%)
Urban	10 (2%)
ASIA impairment scale (AIS), *n* (%)	
A	292 (71%)
B	57 (14%)
C	55 (13%)
D	6 (2%)
Type of injury, *n* (%)	
Paraplegia	235 (57%)
Tetraplegia	175 (43%)
Cause of injury, *n* (%)	
Traumatic	390 (95%)
Nontraumatic	20 (5%)
Ability to read and write Bangla, *n* (%)	
Good ability	146 (35%)
Limited ability	143 (35%)
No ability	121 (30%)

*These are Bangladeshi divisions that include cities and large surrounding rural areas

Table 2 The work status and size of participants' ($n = 410$) families prior to injury

Family details	
Size of families, median (IQR)	5 (4–6)
Number of children in each family, median (IQR))	2 (1–2)
Number of adults in each family, median (IQR)	2 (1–3)
Total number of family members including participants, *n*	2212
Paid work status of participants at time of injury	
Full-time employment (>30 h per week), *n* (%)	335 (82%)
Part-time employment (<30 h per week), *n* (%)	10 (2%)
Unpaid work status of participants at time of injury	
Home duties, *n* (%)	20 (5%)
Student, *n* (%)	38 (9%)
Other, *n* (%)	7 (2%)
Types of work	
Manual labourers (light and heavy)	200 (58%)
Small business	43 (12%)
Tradesperson	60 (17%)
Office worker	23 (7%)
Shopkeeper	10 (3%)
Professional	9 (3%)
Number of families in which participant was the only income earner, *n* (%)	206 (50%)
Number of families in which participant was the main income earner, *n* (%)	302 (74%)

Table 3 The financial situation of participants ($n = 410$), households and family members* before and after injury

	Before injury	After injury
Income (US$ per month; median and IQR)		
Participants	106 (60–180)	–
Households	156 (96–240)	0 (0–102)
Family members	30 (19–48)	0 (0–18)
Living below poverty line (*n*, %) (less than US$57 per month or US $1.90 per day)		
Participants	86 (21%)	410 (100%)
Households	329 (80%)	397 (97%)
Family members	1833 (83%)	2160 (98%)
Living below extreme poverty line (*n*, %) (less than US$37.50 per month or US$1.25 per day)		
Participants	76 (19%)	410 (100%)
Households	262 (64%)	372 (91%)
Family members	1473 (67%)	2018 (91%)

*Including participants ($n = 2212$)

family member above the extreme poverty line. That is, after injury, 91% of family members were living below the extreme poverty line of US$37.50 per person per month.

Discussion

This study investigated work-related family incomes before and immediately after SCI in Bangladesh with the aim of determining the degree of impoverishment of people with SCI and their families. A notable finding was just how impoverished families were prior to injury: families had a median (IQR) income of US$30 (US$19–US$48) per family member per month. Thus 67% of family members were living below the extreme poverty line prior to injury. It was not surprising to see the median (IQR) income drop to US$0 (US$0–US$18) per month per family member following injury, because those injured where typically young males and 74% were the main income earners for their families. This drop of income placed 91% of families below the extreme poverty line. There are various ways of defining poverty with poverty lines often adjusted for the number of children under the age of 12 years living in a family unit. However, regardless of how poverty is defined, there can be little doubt that our findings highlight the dire financial implications that SCI can have on families in Bangladesh.

Our data on participants' incomes prior to injury are broadly consistent with data from our previous study of a similar cohort discharged from CRP in 2011 [26]. We found in our previous study that participants who were wheelchair dependent at discharge earnt a median (IQR) of US$65 (US $39–US$104) per month prior to injury. In the current cohort, participants earnt a median (IQR) of US$106 (US $60–US$180) prior to injury. The higher income observed in the current study may reflect wage inflation over the intervening 4 years (estimated to be 5.75% per year) [27]. Nonetheless, the incomes of participants of both cohorts were lower than in the general population of Bangladesh. For example, while 67% and 83% of family members in the current cohort lived below the extreme poverty and poverty lines prior to injury, respectively, only 13% and 23% of the general population of Bangladesh are in the same financial situations [13, 28–30]. Similarly, the literacy levels of our cohort (only 35% had a good ability to read and write) were lower than the national literacy rate of 74% [31]. These factors together point to the social disadvantage of our cohort, and probably reflect that those most likely to sustain an SCI in Bangladesh are unskilled labourers from poor rural backgrounds [6, 32].

Our data are not necessarily reflective of all people who sustain an SCI in Bangladesh. Bangladesh has a population of 164 million. While there are no accurate data on the incidence of SCI in Bangladesh, it is likely that the incidence is between 20 and 40 per million [8, 33]. This equates to between 3280 and 6560 people with a new SCI each year. The CRP only admits 400 people with recent SCI per year. So, clearly, many people who sustain an SCI are not admitted to CRP and these people may be different to those

that are. For example, those from higher socioeconomic backgrounds may be admitted to private hospitals or hospitals in other countries. In contrast, those from even poorer backgrounds than our cohort may never get to CRP or never get to any hospital because of economic and social disadvantage.

Our calculations may underestimate the extent of the financial strain placed on families because we did not consider additional costs incurred by families for healthcare services. The medical costs for our participants were largely covered by CRP but nonetheless some participants may have incurred health-related costs before they were admitted to CRP. The situation may be quite different in other LMICs or other parts of Bangladesh. For example, one study from Nigeria found that 41% of participants used 50% of their annual income to meet the acute medical costs of an injured person [17]. This does not include the ongoing costs incurred after discharge from hospital.

Financial hardship following SCI affects all aspects of life and contributes to premature death in both high-income countries and LMIC [34, 35]. Our studies in Bangladesh indicate that 32% of participants who are wheelchair dependent at discharge die within 5 years, primarily from pressure ulcers [36]. The causal links between financial hardship, pressure ulcers and premature death is probably complex but it is plausible that poverty plays a major role.

A reduction in poverty needs to be a major focus of future initiatives to improve the lives of people with SCI and their families in LMIC [16, 37]. The data provided in this study could be used to highlight the financial hardship of people with SCI and their families, and to encourage governments to provide some financial support. In addition, attention needs to continue to be directed at getting those injured back to work. For this purpose, vocational training needs to be at the centre of any rehabilitation program [13, 17]. A study from Nepal found that less than half of those with an SCI had any income many years after discharge from hospital [38]. Our previous study from Bangladesh showed that only 37% of people who were wheelchair dependent on discharge from hospital were employed 2 years after discharge [3] and only 42% were employed 6 years after discharge [26]. Some evidence suggests that those who do gain employment have much lower salaries than they had prior to injury [38].

Vocational training is provided at CRP but unfortunately many barriers to employment need to be overcome. These include wheelchair-inaccessible environments, and the low literacy rates and skill levels of people who are typically injured (see Tables 1 and 2). In addition, discrimination and poor societal attitudes to those with disabilities are still widespread. Often, the best employment option for people with SCI and limited skills is to set up small businesses or shops [16]. This may require a small amount of initial financial assistance. It is also important that young students who are injured are supported to return to their education. In addition, attention could be directed at vocational training for the wives of injured men. The women may require more support than in most countries because in Bangladesh women do not typically work outside the home [6]. However, the employment of wives could help relieve the financial pressures on families.

There are several limitations to this study. The main limitation, as discussed above, is that we cannot generalise our results to all people who sustain SCI in Bangladesh or other LMIC. The second limitation is that while our cohort is largely reflective of those admitted to CRP who survive to discharge and are wheelchair dependent, we were unable to recruit 33 potentially eligible participants (9% of the potentially eligible cohort). This may have introduced a small selection bias. Thirdly, we did not verify what participants told us at the time of discharge about their and their families' income and employment status prior to injury. Participants may not have accurately remembered, or may not have known, or may have perceived that it was within their interests to underestimate their family's incomes. In addition, we did not capture people's assets or money given to people by extended family members or friends. We did not explore families' capacities to be self-sufficient through their own crops and animals. Nor did we ask participants about other potential sources of income from insurance, government, prior savings or other sources, although these sources of income are uncommon in Bangladesh particularly for those working in unskilled jobs. We know from anecdotal evidence that many people sell property and animals or take loans to support their families. The results of this study should therefore be seen within these limitations. Future studies could better explore how families survive on such little income.

In summary, SCI have profound financial implications for individuals and their families, and cause extreme poverty in Bangladesh. This is because those most often injured are young people from low socioeconomic backgrounds who are the main income earners for their families.

Data availability

The authors will consider any reasonable requests to access the data.

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Author contributions MSH, LAH, and RDH conceived the study, wrote the study protocol, attained funding, co-ordinated data collection, conducted data analysis and wrote the draft of the paper. MSI was principal investigator and site coordinator for the trial, collected the data and commented on a draft of the paper. MAR was senior trial manager, collected the data and commented on a draft of the paper. SJ contributed to the study protocol, attained funding, contributed to data analysis and commented on a draft of the paper. SM, VT, FBS, IDC, HSC, LB and RIL contributed to the study protocol, attained funding and commented on a draft of the paper. JVG contributed to the overall coordination of the trial and commented on a draft of the paper. HL, SD and QL commented on a draft of the paper.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval Ethical approval was attained by the Ethics Review Committees of CRP, Bangladesh (CRP-R&E-0401-126), and the University of Sydney, Australia (2015/041). We certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during the course of this research.

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Chapter 8 Process evaluation of the CIVIC trial: understanding the delivery of interventions.

Process evaluation of the CIVIC randomised controlled trial: Community-based interventions to prevent serious complications following spinal cord injury in Bangladesh. This study has been published in a peer-reviewed journal and is presented in its published format.

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We confirm that Mohammad Sohrab Hossain has made the following contributions for this paper:

- Conception and design of the research including literature search
- Collection of data
- Analysis and interpretation of the findings
- Writing the manuscript, critical appraisal of content and response to reviewers

[2]Hueiming Liu and Mohammad Sohrab Hossain shared first authorship

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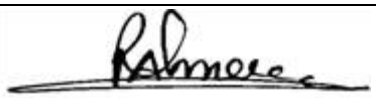
Md. Akhlasur Rahman	
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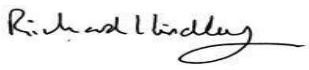
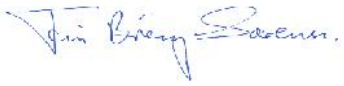
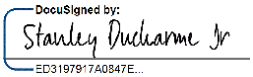
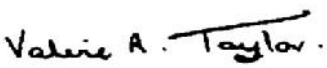
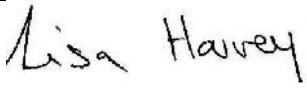
Richard I Lindley	
Fin Biering-Sorensen	
Stanley Ducharme	
Valerie Taylor	
Lisa A Harvey	

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ARTICLE

Understanding how a community-based intervention for people with spinal cord injury in Bangladesh was delivered as part of a randomised controlled trial: a process evaluation

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Abstract

Design Mixed methods study

Setting Community, Bangladesh

Objectives To understand how a community-based intervention for people with spinal cord injury (SCI) in Bangladesh was delivered as part of a randomised controlled trial and to gauge the perceptions of participants and healthcare professionals to the intervention.

Methods A community-based intervention was administered to 204 participants as part of a large randomised controlled trial (called the CIVIC trial). Case-managers followed-up participants with regular telephone calls and home visits over the first 2 years after discharge. The following data were collected alongside the trial: (i) chart audit of telephone calls and home visits (ii) recordings of 20 telephone calls (iii) interviews with 14 Intervention participants and four healthcare professionals including three case-managers.

Results Participants received the target number of telephone calls and home visits. Pressure injuries were identified as a problem during at least one telephone call by 43% of participants. Participants and case-managers valued regular telephone calls and home visits, and believed that calls and visits prevented complications and alleviated social isolation. Participants trusted case-managers and were confident in the care and advice provided. Case-managers expressed concerns that people with SCI in Bangladesh face many problems impacting on well-being and motivation stemming from poverty, limited employment opportunities, societal attitudes and inaccessible environments.

Conclusion A community-based intervention involving regular telephone calls and home visits was administered as intended and was well received by the recipients of the care. Nonetheless, people with SCI in Bangladesh face economic and social problems which cannot be fully addressed by this type of intervention alone.

Introduction

People with spinal cord injury (SCI) in low- and middle-income countries (LMICs) face many challenges when discharged home after their initial injuries. Our recent cohort study of patients discharged from a large hospital in Bangladesh with recent SCI indicated that 20% of those who were wheelchair dependent at discharge had died within 2 years [1] and 32% had died within 5 years [2]. Those who had not died faced ongoing problems with pressure injuries, social isolation, lack of employment, poverty and depression [3]. Similar findings have been reported in other LMICs [4–7]. So clearly there is an urgent

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need to support people with SCI in the community particularly in the first few years post discharge.

In high-income countries, people with SCI are supported after discharge by developed healthcare systems. Typically, people with SCI can return to hospital for regular check-ups, and mobile teams of healthcare professionals can visit and support people with SCI in their homes [8]. Ongoing physiotherapy, counselling and other services may be provided. In addition, people with SCI often have access to sophisticated treatments and rehospitalisation if they develop complications [9–13]. However, such systems of comprehensive care post discharge are not feasible in most LMICs because they are expensive and there is a shortage of healthcare professionals and hospitals with expertise in SCI. In addition, it is difficult for people to get admitted to a hospital if they develop complications because of bed shortages and because often people have to travel long distances to hospitals on poor roads [8].

Our team developed a model of care to support people with SCI after discharge in the community (see Supplementary File 1). It was designed to be affordable and sustainable in Bangladesh. It involves regular telephone calls and home visits over 2 years by specially trained health-care professionals who act as case-managers. Initially an advertisement was placed for any healthcare professionals including nurses for the positions of case-managers but only physiotherapists applied. They were therefore used as the case-managers and reflect the likely workforce for the future if this model of care is effective. At each point of contact between the case-managers and people with SCI, the case-managers screened participants for complications (using a standardised checklist; see Supplementary File 2) and provided ongoing education, psychological support and advice. In addition, each participant was allocated $AU80 for essential goods and services, and provided with an illustrated book that provided guidance on key issues likely to be experienced post discharge (the illustrations catered for participants with limited literacy).

Our model of care (including telephone calls, home visits, $AU80 and an illustrated book) was adapted from evidence-based models used in high-income countries; and drew from evidence about the effectiveness of community-based rehabilitation in LMICs [14] and telephone-based support for people with SCI and other types of disabilities in high-income countries [15, 16]. It was also based on a study where we demonstrated the feasibility of providing advice over the telephone for people with pressure injuries in a clinical trial involving 120 people from India and Bangladesh [17]. We also conducted a pilot study, which found that this model of care could be feasibly delivered [18] by the Centre for the Rehabilitation of the Paralysed in Bangladesh (CRP): a hospital which largely serves the poor and disadvantaged with most coming from rural areas in Bangladesh and working as labourers prior to injury [19]. The full intervention is being tested in a large definitive randomised controlled trial of 410 people with recent SCI (the CIVIC trial [20]). Data collection were completed in February 2020 and are currently being analysed.

The full protocol for the process evaluation has been described in-depth elsewhere [21]. It is based on the UK Medical Research Council guidance [22] and outlines the plan to combine qualitative and quantitative data for an in-depth description of what happened on the ground. The two key components of the framework underpinning the process evaluation address many questions related to how the intervention was delivered (implementation) and how the intervention may or may not have achieved its effect (mechanism of action) taking into account the Bangladeshi situation (context). In this paper, we specifically address the first set of issues around implementation as per the protocol, namely:

- was the intervention delivered as intended?
- what was the nature of the support and advice provided by the case-managers?
- what type of issues were identified during each interaction between case-managers and participants?

Hence, the aim of the study was to understand how our community-based intervention was administered ‘on the ground’ and gauge the perceptions of the participants and healthcare professionals to the intervention.

Methods

Trial design

The CIVIC trial is an assessor blinded randomised control trial in which 410 people who were wheelchair dependent and about to be discharged from CRP in Bangladesh following recent SCI, are randomised to either usual care (control, $n = 206$) or usual care plus our model of care (intervention, $n = 204$) for 2 years after discharge. The primary outcome is mortality at 2 years and secondary outcomes are pressure injuries, other SCI complications (such as urinary tract and respiratory infections, depression), quality of life and participation. The trial was prospectively registered (ACTRN 12615000630516, Universal Trial Number U1111-1171-1876)) and the protocols for the study [20], statistical analysis [23] and process evaluation [21] have been published. Ethical approval for all aspects of the trial including the data presented in this paper was attained from the ethics committees of the CRP, Bangladesh and the University of Sydney, Australia. The CIVIC trial commenced in July 2015 and the last participant was randomised in March 2018.

Data collection was completed in February 2020 but the effectiveness analyses have not yet been completed or reported, and all but two authors remain blinded.

Setting

All participants (control and intervention) of the CIVIC trial received standard inpatient rehabilitation at CRP prior to discharge (and randomisation) and usual care after discharge. Inpatient rehabilitation included training in mobility, bladder and bowel care, vocational training, and guidance on ways to find employment and be independent at home and in the community. Usual care after discharge was variable but data collected as part of the CIVIC trial indicated that all participants (control and intervention) had a median (interquartile range) of 2 (1–5) telephone interactions with staff from CRP, and were visited by CRP staff a median (IQR) of 1 (0–2) times over the first 2 years following discharge. Participants were not routinely brought back to CRP for an outpatient follow-up after discharge and readmission for management of problems was rare because CRP had limited bed capacity and participants could not readily travel to CRP.

Data collection for the process evaluation

Quantitative data

Three sources of quantitative data were collected.

Source 1: The duration and number of telephone calls and home visits made to the 204 Intervention participants. These data were derived from the trial records: trial staff recorded the date and duration of each telephone call and home visit (see Supplementary File 2).

Source 2: The number and types of problems identified during the telephone calls and home visits to the 204 Intervention participants. These data were derived from the trial records: trial staff used a checklist to record these data (see Supplementary File 2).

Source 3: The types of equipment and services purchased for the 204 Intervention participants. Each participant was allocated $AU80 for miscellaneous items as required. Details records were kept on how this money was spent.

Qualitative data

Three sources of qualitative data were collected.

Source 1: Recordings of 20 routine telephone calls provided by the case-managers to Intervention participants: The telephone calls were randomly selected from all Intervention participants on the trial at the time of data collection (December 2018) stratified by tetraplegia vs. paraplegia, many health problems vs. micnimal health problems (as categorised by trial staff based on their chart records), and discharged in the preceding year vs. discharged more than 1 year prior. The telephone calls were conducted by the case-managers in Bangla and were later translated and transcribed into English by a team of bilingual physiotherapists.

Source 2: Interviews with healthcare professionals: MSH, LAH and HL interviewed three (of six) case-managers responsible for providing the intervention to participants, and HL interviewed another healthcare professional involved in the management of the trial between December 2018 and March 2019. Another 12 healthcare providers and stakeholders from CRP and other parts of the country, including policy makers and service providers were also interviewed but their data are not reported in this paper. The interviews were semi-structured using an interview guide and were conducted in English (see Supplementary File 3a). The healthcare professionals were asked to reflect on issues such as: *What were the main issues discussed during the telephone calls and home visits? What were some of the biggest problems people with SCI face after discharge? Did they think people with SCI did/ would value regular contact with healthcare professionals after discharge?*

Source 3: Interviews with Intervention participants: One of the authors (MSH) interviewed 14 participants from the Intervention group in their homes between December 2018 and March 2019 (6 participants from the Control group were also interviewed but their data are not reported in this paper). The person conducting the interviews knew that the participants were in the Intervention group. All Intervention participants had either completed the trial or were currently on the trial and were categorised by trial staff as tetraplegia vs. paraplegia, many health problems vs. minimal health problems (based on participants' chart records), and discharged in the preceding year vs. discharged more than 1 year prior. Fourteen were then randomly selected to ensure representation from each category although subsequently three randomly selected participants who lived in a very remote part of Bangladesh were replaced with another three participants who lived closer to CRP to minimise travel. Participants were initially telephoned, invited to participate (none declined), and then interviewed in person in their homes. The interviews were semi-structured using an interview guide (see Supplementary File 3b). The participants were asked to reflect on the following issues: *Did they value the regular contact with the case-managers? Did the intervention help them and if so how? What were some of the biggest problems they faced post discharge?* The interviews were conducted in Bangla and later translated and transcribed into English by a team of bilingual physiotherapists.

Table 1 Characteristics of Intervention participants whose telephone calls with their case-managers were recorded and characteristics of the Intervention participants and healthcare professionals who were interviewed.

	Intervention participants whose telephone calls were recorded ($n = 20$)	Intervention participants who were interviewed ($n = 14$)	Healthcare professionals who were interviewed ($n = 4$)
Age, years	35 (26–44)	39 (29–47)	34 (29–40)
Gender, M:F, *n*	18:2	11:3	3:1
Years of experience, years	–	–	11 (5–16)
Time since injury, years	2.2 (1.7–2.6)	2.6 (2.2–3.4)	–
Time since discharge, years	1.5 (1.2–2.0)	2.1 (1.6–3.0)	–
Tetra vs. para, *n*	9:11	9:5	–
Minimal vs. many problems, *n*	12:8	13:1	–

All data are counts, except data for age and time variables which are reported as medians (interquartile ranges).

Analysis

Recordings of the telephone calls and interviews were analysed by the authors (LAH, MSH and HL), who have backgrounds in physiotherapy, public health and medicine, and varied experience in qualitative research. The data were managed with NVivo version 11. The authors read transcripts of telephone calls and interviews, and coded the transcripts line-by-line. Four transcripts were coded together after an in-depth discussion to better understand the background of the telephone calls and interviews, and to clarify any issues related to local context and culture. Analysis was both deductive and inductive using an overarching framework with major nodes of context, mechanisms, implementation and outcomes (as per the protocol for the process evaluation [21]), and iterative analysis of the data was conducted to form new codes. After making changes to the coding framework (Supplementary File 4), and analysing seven more transcripts together, the remaining transcripts were divided and coded separately. Weekly meetings were held over a 4-month period to discuss the analysis and clarify concepts. For this paper, all data coded to the tree node 'mechanisms' of the CIVIC intervention were re-analysed using a constant comparison approach of different perspectives [24].

The quantitative data were collated and tabulated. Key themes were triangulated with descriptive statistics obtained from the quantitative data to provide a better understanding of how the model of care was administered 'on the ground' and gauge the perceptions of the participants and healthcare professionals to the intervention.

Results

A median (IQR) of 38 (36–40) telephone calls lasting a median (IQR) of 9.8 min (8.6–11.1), and a median (IQR) of 3 (3–3) home visits lasting a median (IQR) of 2.0 h (1.9–2.2) were provided to the 204 Intervention participants. The characteristics of the 14 Intervention participants and four healthcare professionals who were interviewed, and the 20 Intervention participants whose telephone conversations with case-managers were recorded, are shown in Table 1. Our findings are organised into key themes with the supporting quantitative findings (details in Table 2 and Supplementary files) embedded within the main text. Additional illustrative quotes are provided in Supplementary File 5.

Table 2 Summary of the chart audits of the Interactions between case-managers and Intervention participants ($n = 204$) during the telephone calls and home visits.

	Telephone calls	Home visits
Acute illness/fever	51%	7%
Skin	43%	30%
Bladder	36%	14%
Depression	34%	16%
Burning sensation/pain	29%	12%
Sleep, appetite or mood	28%	16%
Bowel	26%	16%
Spasticity	23%	11%
Pain	18%	9%
Swelling	17%	12%
Urinary tract infections	16%	3%
Miscellaneous	12%	7%
Autonomic dysreflexia	5%	5%

The most common "miscellaneous" problems were those related to sexual and respiratory function, hypotension and visits to traditional healers.

Data include the number (%) of participants who reported experiencing the following problems on at least one telephone call or one home visit.

Theme 1: Prevention and management of pressure injuries was a major focus of telephone calls between the case-managers and intervention participants

It was apparent that pressure injuries were a major focus of the telephone calls between the case-managers and

Intervention participants (See Table 2). Pressure injuries and bladder-related issues were identified by case-managers or Intervention participants as a problem during at least one telephone discussion by 43% and 36% of participants ($n = 204$), respectively. Analysis of the recorded telephone calls highlighted that case-managers often talked about strategies to treat and prevent pressure injuries. These strategies were not different to what participants had been taught as inpatients at CRP prior to discharge. However, some participants indicated they had forgotten what they had been told to do at CRP, and that the regular telephone calls with their case-managers were helpful reminders. This is a typical comment provided by a participant:

"*If I have any problems related to my health or I see any blackish spots on my back then I share them with him (the case-manager). Then he guides me about how I should take care of my problems. Sometimes he discusses with me in-depth about why I am getting these problems. For example, sitting or lying in the wrong position. He advises me on how I should lie or sit. He teaches me these types of things, so I feel good. I also feel good that I can share my problems with him.*" (Participant with tetraplegia and minimal health problems).

It was not always easy for case-managers to help participants with pressure injuries over the telephone. In particular, case-managers described how sometimes participants under-reported pressure injuries and it was difficult for case-managers to gauge the seriousness of the situation. Case-managers tried to overcome this by encouraging participants, where possible, to send photographs of pressure injuries by smartphone. However, this strategy was not widely implemented because either participants did not have smart phones or it was too costly for them to send images. In addition, case-managers spoke to family members to confirm participants' reports. Case-managers also discussed how it was impossible for some participants to follow their advice. For example, some participants did not have adequate family support to help lift or turn them regularly. Others were advised to remain on bedrest but were unable to comply because they needed to work to support their families. The case-managers also reported feeling helpless once pressure injuries became severe. In these cases, the case-managers would call upon the expertise of other staff at CRP to guide them and the participants. They also spoke directly to family members to help them with dressings and to provide support. Case-managers often tried to help participants access available local services or gain readmission to CRP but reported that often they could not find appropriate health services to assist or could not get participants readmitted to CRP because of limited bed availability. In some cases, participants were offered a bed at CRP but could not travel the long distance required to get there. Similarly, some participants expressed frustration at the lack of SCI expertise at their local hospitals.

"I discussed this with the [case-manager]. He told me that if I was unable to come to Dhaka [location of CRP] then I needed to get admitted to a nearby medical centre. So I went to [name withheld] medical centre late one night at 3am … They didn't know anything … I was admitted to the hospital for ten days but the doctor did not once advise me to change my body position … They don't have any idea about SCI…" (Participant with tetraplegia and minimal health problems).

Case-managers stated that some participants were very depressed and lacked hope for the future. They felt that this sometimes prevented participants from heeding the case-managers' advice and being pro-active in treating and preventing their pressure injuries.

Theme 2: Participants and the case-managers valued the home visits although they were logistically difficult to conduct

Home visits were highly valued by case-managers. Home visits enabled case-managers to further assess participants' home environments and equipment (e.g. type of mattress) and identify environmental and structural barriers (e.g. steps). Case-managers also valued the opportunity to directly assess participants (e.g. look at their skin) and to directly provide recommendations to address observed barriers and problems. Home visits also gave case-managers an opportunity to raise awareness in the community about supporting people living with disabilities. This was possible because often community members would be supportive and curious about the home visits, and come to participants' homes when the case-managers were present. Importantly, some participants stated in the interviews that the home visits made them feel special and cared for.

A case-manager summarised the benefits of the home visits with this statement:

"…when we visited the patients' homes, they could see our faces and we could share our facial expressions. Also, when I saw a person's family condition then I had a better understanding of the problems and more sympathy. Also, during the home visits, the patients started to trust me. As I said earlier, some patients initially hid their problems from me after discharge [when speaking on the telephone]. So, through the home visits I could see the situation and home environment. I tried to modify their home environments." (Case-manager)

However, case-managers also noted that the home visits required significant effort, time and organisation. Some home visits required 1–2 days of travel. The travel was particularly challenging for a female case-manager because it is unusual and difficult for women in Bangladesh to travel alone outside their home communities and particularly after sunset. In addition, case-managers stated that sometimes

they worried about accidents while travelling because of the poor roads and the need to travel long distances using cars, motorbikes and ferries.

Theme 3: Telephone calls and home visits helped alleviate a sense of social isolation and depression

All the participants described how the initial few weeks after discharge from CRP were extremely difficult as they tried to adjust to their new lives. The regular telephone calls and home visits provided participants with a link back to the safe and inclusive environment of CRP. Participants described how the telephone calls helped to reduce their sense of social isolation as they valued speaking to people who were comfortable in discussing their problems and who had an in-depth understanding of their challenges. In comparison, some participants described how people in their local communities did not know how to talk to them, and treated them differently than prior to their injuries, and how families and community members became tired of being asked for constant 'favours' such as help with transfers or financial assistance. A participant reported:

"*We may not have any communication with anyone other than with them [their case-managers]. This makes us feel good…*" (Participant with tetraplegia and minimal health problems)

Case-managers tried to address social isolation and encourage active community participation where possible. For example, they encouraged participants to go outside their homes and attend their local mosques. This was more feasible for some participants than others because it was dependent on family support and wheelchair access. Some participants described social isolation due to family breakdowns, during which the case-managers would try to intervene and support spouses and family members encouraging them to stay together, if and where appropriate.

Theme 4: Case-managers inspired trust and confidence, though setting up an action plan with participants was an unfamiliar approach that became more familiar over time

Participants appeared to have trust and confidence in their case-managers which seemed to be facilitated by the rapport built between the case-managers and participants over time, but also through the case-managers' clinical expertise, and provision of the allocated $AU80 for essential equipment (see Supplementary File 6). Case-managers used an informal and conversational approach to build rapport with participants. For example, the case-managers often started telephone conversations by asking participants if they had eaten, and from there they would do a quick assessment of nutritional intake and provide locally relevant suggestions for dietary changes including vegetables which were currently in season. The case-managers often asked after the wellbeing of family members as a way of gauging whether carers were around, and what supports were available.

A key aspect of the intervention was screening for problems and setting up action plans in collaboration with participants i.e. joint goal setting. This differed from the usual approach in Bangladesh, where health providers typically dictate the actions to be taken in a non-negotiable manner. In contrast, in the CIVIC trial, case-managers were encouraged to facilitate a goal setting process where participants set their own goals, reflected on how to achieve their goals through an action plan, and regularly reviewed progress with case-managers. The goals were diverse and ranged from better skin management to community or family participation. At the beginning of the trial, case-managers had little experience helping people set goals and plans of action. Neither were participants familiar with this approach; as most participants expected case-managers to provide them with information. For this reason, case-managers initially required training in this approach and in general principles of psychology. Case-managers reported feeling more confident with this approach as the trial progressed. They described moving from a "*telling the participants what to do approach*" (based on a provided checklist) to a goal setting approach. Case-managers stated that during the early days of the trial they were frustrated because participants did not listen to or heed their advice. They described how they grew to better understand the many reasons why participants did not always adhere to advice, and they became less critical in the way they interacted with participants. Instead, over time, the case-managers became better at encouraging participants to self-reflect on their problems and possible solutions, and to set goals that took into account competing priorities.

This quote illustrates the reflections of a case-manager on his/her role in facilitating and enabling participants to develop an action plan:

"*Lots of patients have opportunities but there is nobody for them to discuss opportunities with them. Nobody has time to talk with them… We let (the) patients know about the sorts of opportunities they have for their future.*" (Case-manager)

Theme 5: Limitations of the financial allowance and opportunities for employment

The provision of $AU80 was mainly intended to support the prevention and management of serious complications through the provision of basic equipment (e.g. bladder supplies; see Supplementary File 6). However, it was apparent that while this $AU80 was greatly valued, the participants and their families faced significant financial difficulties, which this amount of money could not relieve. The analysis of our records showed that the mean (SD)

amount of the allowance expended per participant was $AU73 ($19). Most of these funds were spent on bladder-related equipment such as catheters, urinal bags and lubricant for self-catheterisations (mean, $AU59 per participant). However, all the participants who were interviewed stated that they needed greater financial assistance. The same comment was repeatedly made by the four healthcare professionals. Financial support was often needed to setup small businesses that could ensure an ongoing source of income. For example, at a visit to a participant's home, a community leader asked for financial support so that the participant could buy some goats as a source of ongoing income. Other requests included support to procure some initial merchandise so participants could set up small village shops.

The case-managers tried to help participants find work to reduce the financial strain on participants and their families. However, even though most participants had received vocational training at CRP (e.g. training to set up a small business, sew or fix machinery), it was evident that there were limited work opportunities for participants in their home communities, especially for those living in rural areas.

Discussion

The purpose of this study was to examine how our community-based model of care was administered 'on the ground' and to gauge the perceptions of the participants and healthcare professionals to the intervention. Overall our model of care seemed feasible, culturally appropriate and valued by the participants and healthcare professionals. There was a strong focus on the prevention and management of pressure injuries through the telephone calls and home visits. Home visits were logistically difficult but were valued by the case-managers and participants. Ongoing regular contact between case-managers and participants partially alleviated participants' sense of social isolation and depression. Looking across the themes, participants appeared to invest trust and confidence in case-managers, who were often required to address complex clinical, psychological and social problems.

There are four key implications from our key themes for those considering rolling out our model of community-based care in similar settings: First, our intervention built on the education participants had already received at CRP prior to discharge. Therefore, the advice and education provided over the telephone was not always new for participants. The regular contact with the case-managers did, however, serve to reinforce and remind participants of what they had previously learnt, and encouraged participants to look after themselves. It is possible this intervention might not be helpful in situations in which participants had not received prior education at a specialised SCI centre such as CRP, but it is also possible that the intervention could be of more value in these situations. This is an example of the potential importance of 'contextualisation' of the results of randomised controlled trials to local factors that may influence outcomes [22].

The second key implication was the importance of the home visits. Home visits were logistically difficult to conduct. That might not be the same for all LMICs because Bangladesh has a very decentralised population. Most participants lived in rural locations with poor transport infrastructure. The CRP is already working on decentralising their SCI services so that travel to people's homes is less burdensome for staff. This model—one in which satellite SCI services are attached to a larger centrally located SCI centre—is used elsewhere in the world, including in other LMICs such as Vietnam (personnel communications with staff from Handicap International). In addition, CRP is introducing the use of 'telehealth' with greater use of face-to-face interactions. However, decentralisation requires maintenance of a skilled workforce at multiple sites, which can be difficult to achieve when skills, support and training opportunities are concentrated centrally. Many of these issues are discussed in the recent World Health Organization report on rehabilitation in health systems [25].

The third key implication of our findings was the importance of the skills and expertise of case-managers. We used physiotherapists with strong clinical backgrounds in SCI and a good understanding of nursing issues including basic care for the bladder, bowel and skin. They received training from psychologists, nurses and doctors prior to the trial. We initially planned to employ a variety of healthcare professionals as case-managers, but only physiotherapists applied for the positions. This reflects the availability of physiotherapists in Bangladesh. They are generally well trained in SCI and capable of providing general advice for nursing and medical problems. However, despite specific training, the case-managers lacked some of the specialist knowledge and skills of well-trained nurses, psychologists and other healthcare professionals. We see this as an inevitable consequence of limited resources.

A particularly important skill required of case-managers is the ability to support behaviour change. Recent rehabilitation studies have highlighted the value of behaviour change approaches and the use of a behaviour change wheel in the systematic development of complex interventions that require changes in participant behaviour and capability [26]. We tried to encourage a behaviour change approach and goal setting but case-managers were initially unfamiliar with both. They required training and support to be able to facilitate patient centred care that was different to the usual culture of delivering healthcare in Bangladesh. Our impression is that it may be more difficult to implement behaviour change approaches and goal setting in this

context as compared to caring for people with SCI in high-income countries. Nonetheless, the case-managers were highly motivated and devoted, and very good at developing rapport, trust and a strong therapeutic relationship with the participants; all of which are key to improving people-centred services [27]. It is not clear how easy it would be to employ staff of a similar calibre if the intervention were to be rolled out on a large scale in Bangladesh and other countries. Clearly, the skills and personal qualities of the case-managers may influence the effectiveness of the intervention.

Lastly, the financial strain on participants and their families was a reoccurring challenge that could limit the effectiveness of support provided by case-managers. In LMICs such as Bangladesh, those with SCI and their families often live in extreme poverty. We found that 65% of patients admitted to CRP in 2011 were living below the poverty line when followed up 6 years later [28], and that 91% of the families of participants in the CIVIC trial were thrown into extreme poverty by the loss of the person's income [19]. This highlights the pressing need of these people and their families for financial assistance after injury, as was also noted in the 2013 World Health Organisation Report on SCI [8]. Looking ahead, it is likely that wider programs of social support and financial protection will be required alongside the design of innovative culturally appropriate programs such as the CIVIC community-based intervention to sustainably address the needs of this marginalised population [29].

Our study had several important strengths. It was undertaken alongside a rigorously conducted trial with pre-specified trial protocol, statistical analysis plan and process evaluation plan. Importantly, to reduce bias, all but two of the investigators remained blind to the trial results which were expected in March 2020. However, the present study is not without its limitations. First there is the potential for positive reporting bias because MSH and LAH helped design the intervention and MSH worked at CRP for many years. This risk was mitigated by the involvement of HL who is an external evaluator. It was also mitigated by the strong emphasis on researcher reflexivity. Second, the recordings of the telephone calls were conducted later in the trial, by which time case-managers had become more experienced. It would have been helpful to have captured some early telephone interactions. None of the telephone calls were conducted with recently discharged participants whose problems may have been greatest. Lastly, we did not interview all the case-managers or the carers of the participants who had died or had poor outcomes. The later may have provided some helpful insights into what went wrong in those cases. We will address these issues in a post-hoc process evaluation that will triangulate findings of the process evaluation with the primary effectiveness analysis of the trial.

The CIVIC trial aims to reduce the high levels of mortality and serious complications in people from LMICs living with SCI. Irrespective of the final results of the CIVIC trial, we hope this process evaluation will help those working in LMICs to design programs to support people with SCI and other disabilities in the community following discharge.

Data availability

The authors will consider any reasonable requests to access the data.

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Author contributions MSH, LAH and RDH were primarily responsible for the CIVIC Trial. MSH, HL, LAH and SJ conceived the protocol for the process evaluation. MSH conducted all interviews. MSH, HL and LAH designed the interview guides, conducted the interviews with the healthcare professionals, designed the coding framework, coded the data, met regularly to analyse the data, and wrote the draft of the paper. MSI, MAR and PDC assisted with data collection, provided the intervention or coordinated the trial, and commented on a draft of the paper. All other authors contributed to the full CIVIC trial proper and commented on a draft of the paper.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval Ethical approval was attained by the Ethics Review Committees of CRP (CRP-R&E-0401-126) and the University of Sydney, Australia (2015/041). A separate ethical permission was taken from CRP-EC (CRP-R & E-0401- 230) to interview the participants for this process evaluation. We certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during the course of this research.

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Chapter 9 Results of the CIVIC trial

CIVIC randomised controlled trial: Community-based interventions to prevent serious complications following spinal cord injury in Bangladesh.This study has been accepted for publication in a peer-reviewed journal and is presented in its submission format.

Published manuscript:

Mohammad Sohrab Hossain, Lisa A Harvey, Md. Shofiqul Islam, Md. Akhlasur Rahman, Stephen Muldoon, Fin Biering-Sorensen, Stephen Jan, Hueiming Liu, Qiang Li, Ian D Cameron, Valerie Taylor, Richard I Lindley, Laurent Billot, Robert D Herbert. Community-based interventions to prevent serious complications and premature death after spinal cord injury in Bangladesh (CIVIC): a randomised trial. Accepted for publication on 12th Aug 2020, Spinal Cord.

Conference proceedings:

This study has been presented at a conference. It appears in the conference proceedings as:

- Hossain MSet al. (2017). Community-based care for reducing mortality and improving quality of life after spinal cord injury in Bangladesh: a 3-year update on the CIVIC trial. *Asian Spinal Cord Network*, Chiang Mai, Thailand.

Publication statement: Statement from co-authors confirming the authorship contribution of the PhD candidate.

Mohammad Sohrab Hossain,Lisa A Harvey, Md. Shofiqul Islam, Md. Akhlasur Rahman, Stephen Muldoon, Fin Biering-Sorensen, Stephen Jan, Hueiming Liu, Qiang Li, Ian D Cameron, Valerie Taylor, Richard I Lindley, Laurent Billot, Robert D Herbert. Community-based interventions to prevent serious complications and premature death after spinal cord injury in Bangladesh (CIVIC): a randomised trial. Accepted for publication on 12th Aug 2020, Spinal Cord.

We confirm that Mohammad Sohrab Hossain has made the following contributions for this paper:

- Conception and design of the research including literature search
- Collection of data
- Analysis and interpretation of the findings
- Writing the manuscript, critical appraisal of content and response to reviewers

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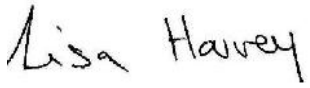
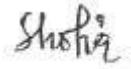
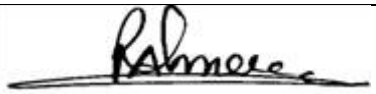
Lisa A Harvey	
Md. Shofiqul Islam	
Md. Akhlasur Rahman	
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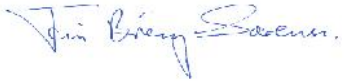
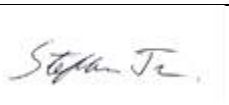
Fin Biering-Sorensen	
Stephen Jan	
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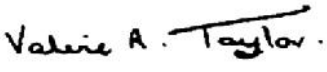
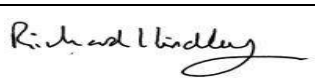
Valerie Taylor	
Richard I Lindley	
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A community-based intervention to prevent serious complications and death two years after discharge in people with spinal cord injury in Bangladesh (CIVIC): a randomised trial

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Abstract:

Study design: Randomised Controlled Trial.

Objectives: To determine the effectiveness of a sustainable community-based intervention designed to prevent serious complications and death two years after discharge in people with spinal cord injury in Bangladesh.

Setting: Bangladesh.

Methods: A pragmatic randomised trial was undertaken. People who had sustained a spinal cord injury in the preceding two years, were wheelchair-dependent, and were about to be discharged from hospital in Bangladesh were recruited and randomised to an Intervention or Control group using a concealed allocation procedure stratified by level of lesion (tetraplegia/paraplegia). Participants in the Intervention group received 36 phone calls and three home visits over the first two years following discharge. All participants received usual post-discharge care. Survival status and date of death were determined by blinded assessors two years after randomisation.

Results: Between July 2015 and March 2018, 410 participants were randomised (204 to Intervention, 206 to Control). There was no loss to follow up. At two years, 15 (7.4%) participants in the Intervention group and 16 (7.8%) participants in the Control group had died (hazard ratio from unadjusted Cox model = 0.93 [95% CI, 0.46 to 1.89]; p from log rank test 0.85). There were no clinically important or statistically significant average causal effects of intervention on the incidence or severity of complications.

Conclusion: A program of community-based care for people with recent spinal cord injury in Bangladesh involving frequent phone contact and occasional in-person contact with a health professional after discharge from hospital is no better at preventing death at two years than usual care.

Trial Registration: ACTRN12615000630516; U1111-1171-1876.

Introduction

In low- and middle-income countries, people who sustain spinal cord injuries are likely to experience serious complications after discharge from hospital. Common complications include pressure ulcers, respiratory and urinary tract infections, depression, faecal and urinary incontinence, and autonomic dysreflexia [1, 2]. These complications can be life-threatening [2, 3]. We found that 19% of wheelchair-dependent patients with spinal cord injury discharged from a large hospital in Bangladesh were dead within two years of discharge [4] and 31% were dead within five years [5].

Mortality rates after discharge from hospital in low- and middle-income countries are much higher than in high-income countries [2, 3]. That may be because in most high-income countries structured follow-up programs are used to prevent and manage secondary complications [2, 6]. These programs typically involve regular face-to-face follow-up with clinicians who screen for complications and provide advice and support. In high-income countries, most people with spinal cord injury have ongoing access to medical care and can be hospitalised if required [2, 7, 8]. In contrast, follow-up services are not routinely available in many low- and middle-income countries because the cost of providing such services is prohibitive and because travel to clinics and hospitals can be difficult, particularly for people who live in rural areas.

The first-line strategies for prevention and management of common complications after spinal cord injury are neither expensive nor technically difficult to implement. For example, pressure ulcers can be prevented and managed by providing suitable cushions and mattresses and regular repositioning [9, 10]. Bladder infections can be prevented and managed with clean, regular self-catheterisation and adequate fluid intake [11]. Whilst most of these

recommended strategies are not based on the results of high quality trials, they are sensible and recommended in all major guidelines [2, 9, 11, 12]. Presumably the strategies are applicable and implementable in both high- and low-income countries.

In an attempt to reduce the rates of secondary complications and death soon after discharge from hospital, we designed an affordable and potentially sustainable community-based program of care for people who had been discharged from hospital with spinal cord injury. A key feature of the intervention is frequent phone contact between health professionals and people with spinal cord injury in the two years after discharge from hospital. The health professionals help people with spinal cord injury identify complications and intervene early, before the complications become severe, and provide advice on simple strategies that people with spinal cord injury can implement themselves to prevent and manage complications.

There is widespread acceptance of the need to provide programs of care for people living with spinal cord injury in low- and middle-income countries [2], but there have been few randomised trials evaluating the effectiveness of those programs. We refined and updated a search conducted as part of a Campbell Systematic Review [13] to identify trials of any type of community-based program for people with spinal cord injury from low- or middle-income countries. The search identified only two trials, both of which were conducted by members of our research team. One trial of 120 participants, conducted in India and Bangladesh, evaluated the effectiveness of a 12-week program of phone-based support for people with spinal cord injury who had developed pressure ulcers [14]. The evidence was suggestive but not confirmatory of a beneficial effect: the intervention reduced pressure ulcer size by, on average, 2.3 cm^2 (95% CI -0.3 to 4.9). The second trial was a pilot trial of 30 people with spinal cord injury followed for two years [15]. It confirmed the feasibility of conducting a

large trial of our community-based program of care. The intervention was further refined prior to undertaking the definitive trial. That trial - the CIVIC trial - is reported here.

The purpose of the CIVIC trial was to determine the effectiveness of a community-based program of care involving frequent phone and occasional in-person contact with a health professional after discharge from hospital with spinal cord injury in Bangladesh. We hypothesised that the intervention would prevent serious complications and death in the first two years after discharge in this population.

Methods

Study design

The CIVIC trial was a pragmatic, assessor-blinded, two-arm, parallel, randomised, superiority trial. The trial protocol and statistical analysis plan have been published [16, 17]. The trial was prospectively registered (ACTRN12615000630516; U1111-1171-1876).

Participants

Patients admitted to the Centre for the Rehabilitation of the Paralysed (CRP) with a recent spinal cord injury were eligible to participate in the trial if they were at least 15 years of age, were wheelchair-dependent on discharge, had sustained a traumatic or non-traumatic spinal cord injury in the preceding two years and provided written consent. The CRP provides specialised inpatient rehabilitation for over 400 people with recent spinal cord injury each year. It accepts patients with recent traumatic and non-traumatic injuries from across Bangladesh irrespective of income. It is the only specialised spinal cord injury centre in Bangladesh and one of the largest rehabilitation centres of its kind. From 12th July 2015, trial staff screened all people with spinal cord injury prior to discharge from hospital.

Randomisation

Participants were randomised in permuted blocks stratified by level of lesion (tetraplegia or paraplegia). The randomisation schedule was concealed from potential participants, trial staff and all investigators, except an Australia-based investigator (RDH) who generated the allocation schedule and two India-based trial staff who dispensed allocations by email. Participants were approached and enrolled by trial staff but allocation was requested by the site coordinator (MSI). Neither the investigator nor the two trial staff had any involvement in recruitment of trial participants. Each eligible participant was randomised to either an Intervention group or a Control group.

Blinding

The nature of the intervention precluded blinding of trial participants and the healthcare professionals who administered the intervention. However, the assessors were blinded. To reduce potential for unblinding, assessors were not permitted to share office space or correspond with other trial staff. Assessors were naïve to the nature of the trial intervention and were trained separately to other trial staff. Trial staff did not share information about the trial with CRP staff or patients.

Procedures

The Intervention group received community-based care in addition to usual care. The Control group received only usual care.

To deliver community-based care, healthcare professionals provided phone-based support to participants fortnightly in the first year and monthly in the second year following discharge

from hospital. In addition, a healthcare professional visited each participant and the participant's family in the home on three occasions: twice in the first year and once in the second year. The health professionals had backgrounds in nursing and physiotherapy.

At each contact (i.e., during each phone call or home visit), participants were screened for pressure ulcers, urinary tract infection, faecal or urinary incontinence, depression, autonomic dysreflexia and respiratory complications. Where available and appropriate, the camera and video facilities of smartphones were used to help monitor complications. If there was any evidence of a complication, the healthcare professional provided advice to the participant and the participant's family about management of the complication and then more closely monitored the participant until the complication had resolved. Where necessary and possible, the healthcare professionals referred participants to local service providers (although our process evaluation indicated that these services were either not available or difficult to access [18]). The advice provided to participants followed international clinical practice guidelines [19-21] modified for the Bangladesh context. In addition, healthcare professionals provided education and emotional support. They encouraged the routine implementation of self-help strategies designed to prevent complications, attempted to reduce psychological distress, and encouraged social engagement. They also sought solutions for mobility and self-care limitations. Participants were encouraged to set goals that were regularly reviewed. The healthcare professionals also interacted with and supported participants' families. At each home visit, the healthcare professionals assessed the participant's home situation, encouraged the use of cushions and mattresses appropriate for preventing pressure ulcers, and reviewed bladder and bowel care protocols. The home visits were also important for establishing rapport between the health professional and participant and for increasing the health professionals' understandings of participants' home environments. On the first home visit,

participants in the Intervention group were provided with a pictorial educational booklet specifically designed for the trial. Participants were also provided with health care products such as wound dressings and urinary catheters to a total of AUD80 (~USD51) if they could not otherwise afford these items (see reference [18] for more details).

Participants in the Control group received only usual care (see ref [18] for details). In brief, usual care did not include routine post-discharge follow-up. However, CRP staff members sometimes phoned patients to provide advice and support, and occasionally CRP staff visited nearby patients in the patients' homes. On completion of the trial, participants in the Control group reported receiving a median (interquartile range) of 3 (1 to 5) phone calls, 1 (0 to 2) home visit from CRP staff, and 1 (0 to 4) contact with other healthcare professionals over the two-year study period.

Outcomes:

Data used to characterise the sample were collected at baseline. These included data on age, time since injury, gender, neurological level, type of SCI (traumatic or non-traumatic), American Spinal Injury Association Impairment Scale (AIS), total motor score, marital status, employment status prior to injury, monthly and family income prior to injury, and anticipated primary care giver post discharge.

All outcomes were measured by blinded assessors two years after randomisation (there was a +/- one-month window for these to be conducted). Initially, the blinded assessor phoned the participant and then travelled to the participant's home to conduct the assessment. If, however, the assessor was informed at the initial phone contact that the participant had died, the assessor interviewed family members over phone. Some of the secondary outcomes were

also assessed at baseline to increase the precision of estimates (ie., prior to randomisation, while participants were still in hospital).

The primary outcome was time to death from any cause. The date of death was obtained by asking family members except one participant (obtained from cousin).

Secondary outcomes were burden of complications, prevalence of pressure ulcers, severity of pressure ulcers, depression, participation, quality of life and independence. The secondary outcomes reflected the prevalence rather than incidence of complications. By measuring prevalence of secondary outcomes at baseline and two years rather than monitoring incidence of secondary outcomes over the two-year period we avoided the need to contact participants in the Control group during the two-year period. That was desirable because any contact between trial staff and Control group participants during the two-year period could have caused contamination of the intervention. All questionnaires used to obtain self-reported outcomes were administered in Bangla under the guidance of the assessor.

The burden of complications was measured using the Spinal Cord Injury Secondary Conditions Scale (SCI-SCS) [22]. This is a 16-item scale. Each item is scored from 0 (did not experience the complication in the last 3 months) to 3 (severe or chronic problem over last 3 months). The score for each item was determined by the assessor after asking the participant any question deemed relevant and physically examining the participant if necessary. The maximum possible total score is 48, where 0 represents no complications and 48 represents severe complications over the last 3 months.

Pressure ulcers were assessed using the Pressure Ulcer Scale for Healing version 3 (PUSH) [23, 24]. The assessor examined the participant's skin and rated any pressure ulcers on a scale of 0 to 17. The rating took into account the area of the pressure ulcer (scored from 0-10 using grid paper manufactured for this purpose), amount and type of exudate (scored from 0 [none] to 3 [heavy], and extent of tissue type (scored from 0 [closed] to 4 [necrotic tissue]). If a participant had more than one pressure ulcer the worst pressure ulcer was assessed.

Depression was assessed using the Bangla version of the Centre for Epidemiologic Studies Depression Scale revised version (CESD-R) [25, 26]. The questionnaire contains 20 items, each scored on a 4-point scale. Each item refers to feelings in the past week. Scores are tallied to a total out of 60. A total CESD-R score of 16 or more is indicative of depression. The questionnaire was administered as a self-reported questionnaire with assistance from the assessor if needed.

Participation was assessed using the Bangla version of the eight participation items of the World Health Organization Disability Assessment Schedule version 2 (WHODAS 2.0) [27].The participant was asked how much of a problem he or she had with each participation domain over the preceding 30 days. Each item is scored on a 5-point scale ranging from none (1 point) to extreme/cannot do (5 points). A total score of 8 represents no problems with community participation and a total score of 40 represents extreme problems with participation. The WHODAS was administered as a self-reported questionnaire with assistance from the assessor if needed.

Health-Related Quality of Life was self-assessed, with assistance from the assessor if needed, using the Bangla version of the Short Form Health Survey-12 (SF12) questionnaire [28, 29].

The SF12 consists of 12 questions each graded on a 2- to 6-point scale designed to measure functional health and well-being from the individual's perspective. Physical component and mental component summary scores were obtained using a standard algorithm developed from a US general population unadjusted for age and gender. Scores were standardised so that a score of 50 represents average functioning with a SD of 10. Higher scores reflect a better quality of life.

Independence was assessed using the self-report version of the Spinal Cord Independence Measure III (SCIM-SR). This is a 17-item test covering key aspects of independence. It rates self-care (4 items), respiration and sphincter management (4 items), and mobility (9 items).[30]. The items are scored on scales ranging from 0-1 through to 0-15 points and summed to an overall score out of 100, where a higher score reflects more independence. The assessors determined the score for each item after interviewing participants.

Participants were also asked if they had got out of bed, got out of their homes and engaged in paid work over the last week. This assessment was only conducted at the two-year assessment. The three questions were self-administered with assistance from the assessor if needed. In addition, participants in both groups were asked how often they had been in contact with CRP staff since discharge from the CRP. Detailed cost data were also collected. Participants were asked at the two-year assessment to estimate spinal cord injury-related out-of-pocket costs they incurred over the preceding two years. These data will be reported elsewhere [18].

Trial fidelity

The healthcare professionals providing the intervention were physiotherapists with clinical experience in the management of spinal cord injury. They were provided with a written study manual and trained by the principal investigators and other professionals with extensive experience in the management of spinal cord injury in low- and middle-income countries. Refresher training was provided as needed. Day-to-day support was provided by the trial investigators based in Australia and other countries. Experienced trial monitors from George Clinical, India visited the CRP on eight occasions to audit compliance with the trial protocol and with the International Conference of Harmonisation Harmonised Tripartite Guideline for Good Clinical Practice (ICH GCP). There was only one change to the protocol: 13 months after the first participant was randomised, the minimum age for participation in the trial was lowered from 18 years to 15 years to increase the rate of recruitment.

Statistical analysis

The sample size was informed by our earlier study which investigated two-year survival after discharge from CRP in a cohort of 350 people with recent spinal cord injury [4]. A sample size of 410 people (205 in each group) provided 80% power (α=0.05) to detect an increase in survival from 83% to 93% with a two-tailed log rank test allowing for a single interim analysis and a worst-case 15% loss to follow up.

Data were analysed by statisticians from the George Institute for Global Health (including QL) using SAS Enterprise Guide version 7.1 (SAS/Stat version 9.4) and replicated by one of the investigators (RDH) using Stata v16. The analyses were first conducted using dummy-randomised data and then, after discrepancies between the two analyses had been resolved, on the data as randomised. An independent Data Monitoring Committee monitored unblinded

outcomes and adverse event data according to a written charter and conducted a formal interim analysis when the first 214 participants had been followed up. The protocol provided an option to terminate the trial early if there were safety concerns but not on the basis of futility.

Data were analysed on an intention to treat basis. All tests were two-sided tests with a critical probability of 5%. The primary analysis compared all-cause mortality in the Intervention and Control groups using the log-rank test. Sensitivity analyses were conducted using a Cox model adjusted for level of lesion, combined tests of restricted mean survival times with and without adjustment for level of lesion (tetraplegia or paraplegia) [31], and tests of the difference in the incidence proportion of deaths at the two-year assessment with and without adjustment for level of lesion (tetraplegia or paraplegia) using log-binomial regression [17]. The size of the effect of intervention was expressed as hazard ratios, differences and ratios of restricted mean survival times at two years, and differences in the incidence proportions of death at the two-year assessment.

The effects of intervention on secondary outcomes were estimated using linear models adjusted for level of lesion. For continuous outcomes, baseline scores were included in the model to increase precision and provide adjusted estimates. For binary outcomes, log-binomial regression was used to estimate the relative risk.

Cox models with interaction terms were used to examine whether the effect of the intervention on survival was moderated by level of lesion (tetraplegia or paraplegia) or age (< 30, 30–50, > 50 years).

Results

Between 12th July 2015 and 19th March 2018, 509 people with spinal cord injury admitted to CRP were screened for inclusion in the trial. Of these, 75 were ineligible to participate and 24 declined to participate so 410 participants were randomly assigned to the Control (n=206) or Intervention group (n=204; Figure 1). There were two protocol deviations: two participants were randomised using the wrong stratum. In both cases the error was picked up within a day and the participants were re-randomised using the correct stratum.

The two groups were similar at baseline (Table 1). Two-year outcomes were measured at a median (IQR) of 24.3 months (24.0 to 24.5) after randomisation. We did not identify any instances of assessor unblinding. All participants were assessed or known to have died at the two-year assessment, so there was no loss to follow-up. Two participants' motor scores were not measured at baseline. These are the only missing data.

The intervention was delivered in a way that was generally consistent with the protocol. Participants in the Intervention group received a median (IQR) of 39 (38 to 40) phone calls (the target was 38) and 3.0 (3.0 to 3.0) home visits (the target was 3). The median duration of phone calls was 10 (IQR 9 to 11) minutes. Participants in the Intervention group reported a similar level of usual care as participants in the Control group (i.e., care provided after discharge from CRP other than the care provided as part of the trial intervention) receiving 2 (0 to 5) phone calls, 1 (0 to 1) home visit from CRP staff, and 1 (0 to 5) contact with other healthcare professionals. More details of the intervention and usual care are provided elsewhere [18].

At the two-year assessment, 15/204 (7.4%) participants from the Intervention group and 16/206 (7.8%) participants from the Control group had died. Figure 2 shows the Kaplan-Meier survival curves. The unadjusted hazard ratio was 0.93 (95% CI 0.46 to 1.89; p value from the log rank test 0.85). None of the sensitivity analyses demonstrated clinically important or statistically significant effects on survival (Table 2). There was no evidence of effect moderation by level of lesion (p=0.51) or age (p=0.44). There were no statistically significant or clinically important differences between groups for any of the continuous secondary outcomes (Table 3) or binary secondary outcomes (Table 4).

To minimise potential for contamination, Control participants were not monitored over the two-year period. Therefore, there are no data on serious adverse events in the Control group. In contrast, participants in the Intervention group were closely monitored. In this group there were 30 serious adverse events in 25 participants. Six participants developed a serious adverse event deemed life threatening and 19 participants required hospitalisation for 24 serious adverse events. The most common serious adverse events were pressure ulcers (10 serious adverse events in 10 participants) and urinary complications (10 serious adverse events in 8 participants). Causes of death were adjudicated using unblinded data after completion of the trial by two physicians (FB-S and IC) using all available documentation. The most frequent causes of the 31 deaths were pressure ulcers (17 deaths, 55%), suicide or refusal to eat or drink (4 deaths, 13%), and respiratory-related illness (3 deaths, 10%).

Discussion

These data suggest that a community-based model of care for people with spinal cord injury in Bangladesh did not prevent secondary complications and death in the two years after discharge from hospital. We interpret the data in this way because the incidence of deaths

was nearly identical in the two groups. The confidence intervals about the primary estimates of effect are quite wide (hazard ratios of 0.46 to 1.89), but sensitivity analyses suggest that if there was any effect of the intervention on survival the effect was small. In particular, the confidence intervals about the ratios of two-year restricted mean survival (0.98 to 1.04) and the increase in two-year restricted mean survival (-0.4 to 0.8 months) suggest clinically important effects are unlikely. Moreover, it would be expected that any effect of intervention would have been mediated by a reduction in the incidence or severity of secondary complications, but there was clearly very little effect of intervention on these outcomes (Table 2). For those reasons we conclude there was not a clinically important effect of the intervention on secondary complications or the risk of death two years after discharge. Of course it is not known whether the intervention improves outcomes more than two years after discharge.

The two-year mortality observed in this trial (7.6%) was substantially lower than the two-year mortality observed in putatively the same population of patients discharged in 2011 (19%) [4]. One explanation could have been that those patients who were eligible to participate in the trial but declined to participate (n = 24), or who self-discharged from hospital before trial staff had an opportunity to invite them into the trial (n = 9), were more likely to die than trial participants. We followed up these 33 people, after obtaining ethical approval and consent to do so, and found that 12 (36.4%) had died within two years of discharge. If these people had been included in the trial the mortality rate across all participants would still have been low (9.7%). In other words, selective recruitment had little effect on the mortality rate. It appears likely, therefore, that mortality rates after discharge from the CRP have decreased since 2011. This could be because better health care is now available to people after hospital discharge, or because there has been a change in the case mix of patients admitted to CRP. A comparison

of the baseline characteristics of participants in the earlier cohort study and the current trial suggests that the two cohorts were similar with respect to socio-economic backgrounds and level of lesion. Regardless of the explanation for the reduction in mortality rates after discharge, the findings of the current trial still hold: the intervention did not prevent secondary complications or death in the first two years following discharge.

We had hypothesised that many of the complications people with spinal cord injury commonly develop could be managed at home with appropriate advice and support, and that regular contact with participants, even if only over the phone, would provide an effective way of identifying complications early so that the complications could be managed before becoming insurmountable. The trial findings refute that hypothesis. Similarly, two recent large trials conducted in India and China failed to demonstrate the effectiveness of community-based programs for people with stroke [32, 33]. This highlights the importance of using rigorous research designs to test the effectiveness of community-based interventions that would be widely expected to be effective.

The failure of the intervention to reduce secondary complications and prevent death two years after discharge might indicate that the prevention and management strategies recommended by the health professionals were not effective, or that the strategies were not implemented well. It could be that strategies that would otherwise have been effective were ineffective in the current context, even though they were implemented well, because they were administered to people living in poverty with few resources, poor nutrition, and limited access to health care. To the extent that is true, effective long-term intervention for this population may require strengthening of economic and health systems. Alternatively, is it possible that the intervention may have been more effective if delivered by nurses or doctors.

We did not employ doctors because of the greater cost. We tried to employ nurses but only one appropriately qualified nurse applied for the position (this person was employed). We do not believe that failure to recruit more nurses was a major limitation because the physiotherapists were comprehensively trained and became skilled at providing the intervention.

Interestingly, even though healthcare costs for participants in the Intervention group were subsidised (maximum AUD80), this did not improve health outcomes. The small amount of financial assistance may however have gone some way to alleviating the financial strain experienced by participants and their families [34]. There may be other beneficial effects of the intervention that were not captured with the measured outcomes. As part of a formal process evaluation, 14 participants from the Intervention group were interviewed. All indicated that the regular phone calls alleviated the sense of social isolation and gave them increased confidence to manage their situations [18].

It is possible that the education participants received prior to discharge rendered the post-discharge support unnecessary. During the period of hospitalisation at the CRP, people with spinal cord injury and their carers were educated about prevention and management of secondary complications. Post-discharge phone-based care may be more effective in other contexts where less education is provided while in hospital.

A limitation of this trial was the failure to verify the exact date of death of participants because Bangladesh does not have a death registry. Participants in the Intervention group were carefully monitored and the dates of deaths were accurately recorded by trial staff. However, there were no equivalent data for the participants of the Control group. Therefore

to avoid a systematic bias, only dates of death collected by the blinded assessors at two years were used for the analyses. The blinded assessors asked families and community members of both groups to report dates of death. These dates may not always have been accurate. However, because the assessors were blinded, it is unlikely that any inaccuracies would have biased the trial's findings. Another limitation was that cause of death was determined using information reported by families. The data suggest that pressure ulcers were a common cause of death although often it was not certain whether participants died with pressure ulcers or because of pressure ulcers.

The finding that the intervention did not produce clinically important reductions in secondary complications or death two years after discharge was disappointing but vindicates the trial. More generally, this finding confirms the importance of assessing effectiveness of health interventions with randomised trials even when there is a strong expectation that the intervention is effective. There remains an urgent need to identify sustainable ways to reduce morbidity and mortality after discharge from hospital with spinal cord injury in low- and middle-income countries.

Data archiving

Deidentified individual participant data and the accompanying codebook are provided in the Supplementary files.

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Statement of ethics

Ethical approval was obtained from the ethics committees of the Centre for the Rehabilitation of the Paralysed (CRP), Savar, Bangladesh and the University of Sydney, Australia. Written consent was obtained from all participants involved in the study. Institutional and governmental regulations concerning the ethical use of human volunteers were followed.

Conflicts of interests

The authors do not have any conflicts of interest to be declared for this study.

Authors' contributions

MSH, LAH, SM, VT and RDH conceived the study. MSH, LAH, SM, FB, SJ, IDC, VT, RL and RDH secured funding. MSH, LAH, SM, FB-S, SJ, HL, IDC, RL, LB and RDH wrote or reviewed the study protocol. MSH, LAH, and RDH coordinated the trial. MSH, MSI, MAR and VT managed or contributed to the management of the site. MSI and MAR provided the intervention. LAH, QL, LB and RDH designed and conducted or contributed to the statistical analyses. MSH, LAH, MSI, MAR, SM, FB-S, SJ, HL, WL, IDC, VT, RL and RDH interpreted the results. MSH, LAH, MSI, MAR, SM, FB-S, SJ, HL, QL, IDC, VT, RL, LB and RDH wrote or reviewed the paper.

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Titles and legends for Figures

Figure 1: Flow of participants through the trial

Figure 2: Kaplan-Meier survival curves for the Intervention and Control groups. At two years, 15 (7.4%) participants in the Intervention group and 16 (7.8%) participants in the Control group had died. The number at risk is shown below the figure. The numbers at two-years reflect that some were assessed prior to the scheduled two-year assessment (there was a +/- one-month window for these to be conducted).

Fig 1: Flow of participants through the trial.

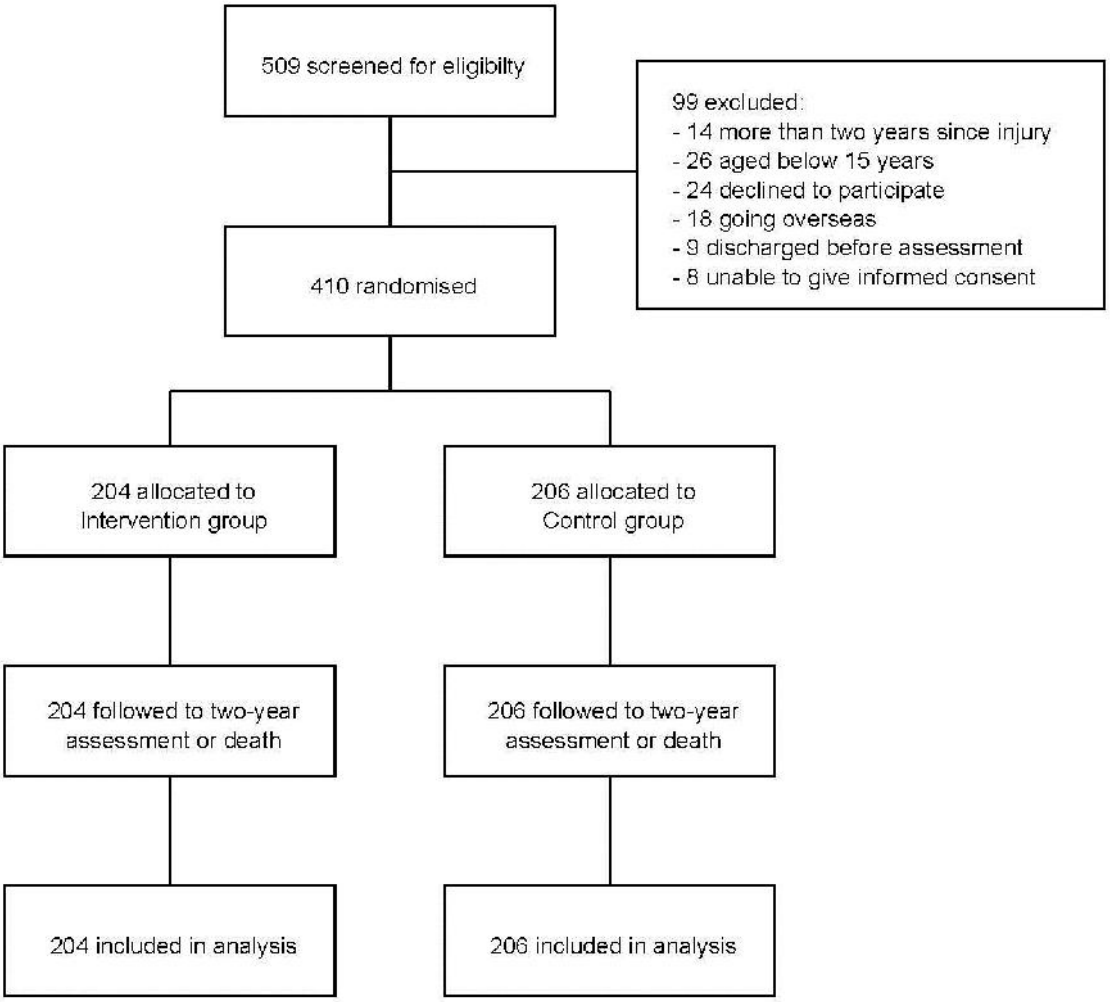

Fig 2: Kaplan-Meier survival curves for the Intervention and Control groups.

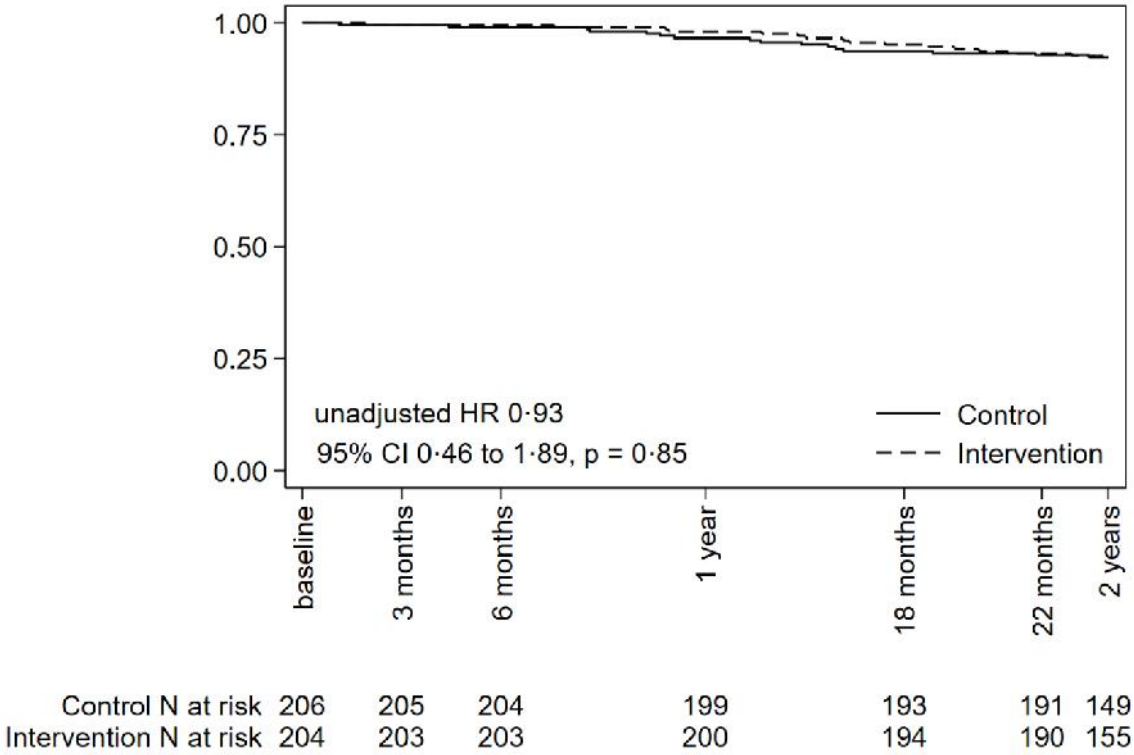

Table 1: Baseline characteristics of participants.

	Control (N=206)	Intervention (N=204)
Age in years		
Median (IQR)	31.4 (24.5 to 41.0)	33.4 (25.7 to 45.0)
Time since injury in months		
Median (IQR)	5.9 (4.6 to 8.2)	5.9 (4.6 to 8.1)
Gender, n (%)		
Male	188 (91%)	181 (89%)
Female	18 (9%)	23 (11%)
Cause of injury, n (%)		
Traumatic	198 (96%)	192 (94%)
Non-traumatic	8 (4%)	12 6%)
Neurological level of lesion, n (%)		
C1 to C4	59 (29%)	61 (30%)
C5 to C8	28 (14%)	23 (11%)
T1 to T7	42 (20%)	34 (17%)
T8 to T12	66 (32%)	80 (39%)
L1 to L5	11 (5%)	6 (3%)
ASIA impairment scale grade, n (%)		
A	148 (72%)	144 (71%)
B	34 (17%)	23 (11%)
C	23 (11%)	32 (16%)
D	1 (1%)	5 (3%)
Total motor score /100		
Median (IQR)	50 (27 to 50)*	50 (29 to 50)*
Marital status, n (%)		
Married	132 (64%)	152 (75%)
Never married	62 (30%)	45 (22%)
Separated / divorced	8 (4%)	7 (3%)
Widowed	4 (3%)	0 (0%)
In paid employment prior to injury, n (%)		
No	30 (15%)	35 (17%)
Yes	176 (85%)	169 (83%)
Monthly income prior to injury in USD		
Median (IQR)	106.1 (58.9 to 176.8)	94.3 (58.9 to 176.8)
Monthly family income in USD		
Median (IQR)	153.2 (88.4 to 235.7)	153.2 (94.3 to 235.7)
Anticipated primary carer post discharge, n (%)		
Spouse	116 (56%)	129 (63%)
Parent	70 (34%)	58 (28%)
Child	4 (2%)	4 (2%)
Other	16 (8%)	13 (6%)

*Two motor scores were missing, one from each group. 1 US Dollar = 84.86 Bangladeshi Taka.
ASIA=American Spinal Injuries Association. All baseline data were collected prior to randomisation and prior to discharge and randomisation.

Table 2 Sensitivity analyses.

Estimand	Method	Estimate (95%CI)	P-value
Hazard ratio	Cox model, no covariates	0.93 (0.46 to 1.89)	0.85
Hazard ratio	Cox model, adjusted for level of lesion	0.94 (0.47 to 1.91)	0.87
Difference in RMST (months)	Method of Cronin et al.[35]	0.20 (-0.39 to 0.79)	0.51
Difference in RMST (months)	Method of Cronin et al.[35], adjusted for level of lesion	0.21 (-0.38 to 0.80)	0.49
Ratio of RMST	Method of Cronin et al.[35]	1.01 (0.98 to 1.04)	0.51
Ratio of RMST	Method of Cronin et al.[35], adjusted for level of lesion	1.01 (0.98 to 1.04)	0.49
Risk difference	Log binomial regression, no covariates	-0.4% (-5.5% to 4.7%)	0.87
Risk difference	Log binomial regression, adjusted for level of lesion	-0.3% (-5.3% to 4.6%)	0.89

Eight pre-specified estimates of the effect of intervention on survival. Hazard ratios were estimated over the two years after randomisation. Risk differences were estimated at the two-year follow-up. RMST=restricted mean survival time at two years.

Table 3: Continuous secondary outcomes.

	Baseline (SD)		Two-year outcome (SD)		Adjusted two-year outcome (SE)		Adjusted effect	
	Control (n = 206)	Intervention (n = 204)	Control (n = 189)[Ŧ]	Intervention (n = 189)	Control (n = 189)[Ŧ]	Intervention (n = 189)	Between-groups (95% CI)	P value
SCI-SCS (/40)	6.0 (2.6)	5.8 (2.8)	7.0 (3.2)	6.7 (2.9)	7.0 (0.2)	6.7 (0.2)	-0.3 (-0.8 to 0.3)	0.39
PUSH (/17)	0.5 (2.0)	0.6 (2.0)	1.4 (3.8)	1.3 (3.5)	1.5 (0.3)	1.3 (0.3)	-0.2 (-0.9 to 0.6)	0.69
CESD-R (/60)	15.9 (9.9)	15.9 (10.1)	17.0 (11.1)	17.0 (10.8)	17.0 (0.8)	17.0 (0.8)	0.0 (-2.1 to 2.1)	1.00
WHODAS (/40)	13.2 (2.8)	13.6 (3.4)	17.9 (5.4)	18.2 (5.3)	18.0 (0.4)	18.2 (0.4)	0.2 (-0.8 to 1.2)	0.69
SF12 PCS	39.9 (4.7)	39.5 (5.4)	36.3 (5.6)	37.0 (6.0)	36.3 (0.4)	37.0 (0.4)	0.7 (-0.3 to 1.8)	0.18
SF12 MCS	48.1 (9.6)	48.4 (9.7)	47.4 (12.9)	47.4 (12.8)	47.5 (0.9)	47.4 (0.9)	-0.1 (-2.6 to 2.4)	0.94
SCIM-SR (/100)	45.0 (19.5)	44.4 (19.0)	50.4 (20.5)	51.4 (19.5)	50.2 (0.8)	51.5 (0.8)	1.3 (-1.0 to 3.6)	0.27

Data are means and SDs, SEs or CIs as indicated. Adjusted outcomes and adjusted effects of intervention (between-group differences) were estimated using linear models with the inclusion of baseline scores and level of lesion to increase precision. SCI-SCS=Spinal Cord Injury Secondary Conditions Scale (lower scores are better). PUSH=Pressure Ulcer Scale for Healing (lower scores are better). CESD-R=Centre for Epidemiologic Studies Depression Scale revised version (lower scores are better). WHODAS=World Health Organisation Disability Assessment Schedule (lower scores are better). SF12 PCS=Physical component score of the Short Form Health Survey-12 (higher scores are better). SF12 MCS=Mental component score of the Short Form Health Survey-12 (higher scores are better). SCIM-SR=Spinal Cord Independence Measure (higher scores are better). [Ŧ] One participant in the control group was alive two years after randomisation but had died by the time his two-year assessment was conducted.

Table 4: Binary secondary outcomes.

	Baseline		Two-year outcome		Effect
	Control (n=206)	**Intervention (n=204)**	**Control (n=189)[Ŧ]**	**Intervention (n=189)**	**Risk ratio (n=204)**
Pressure ulcer	13 (6%)	18 (9%)	27 (14%)	25 (13%)	0.92 (0.56 to 1.53)
Bed-bound	NA	NA	5 (3%)	4 (2%)	0.80 (0.22 to 2.91)
House-bound	NA	NA	54 (29%)	44 (23%)	0.81 (0.58 to 1.14)
Unemployed	NA	NA	139 (74%)	139 (74%)	1.02 (0.92 to 1.13)

Data are number of events (and % of group). Effects of intervention were estimated with log-binomial regression**.** Risk ratios are adjusted for level of lesion. [Ŧ] One participant in the control group was alive two years after randomisation but had died by the time his two-year assessment was conducted. NA=Not Assessed.

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SECTION 4: DISCUSSION and CONCLUSIONS

Chapter 10 Discussion

The Discussion focuses onthe:

- key findings of my studies
- a summary of each study
- facilitators and barriers to conducting high-quality research in Bangladesh
- strengths and limitations of my studies
- suggestions for future research
- implications for clinical practice
- other general recommendationsand
- it draws some broad conclusions from the thesis.

10.1 Key findings of my studies

The primary objective of this thesis was to develop and test the effectiveness of a low-cost community-based interventions to prevent complications and reduce premature mortality for people with SCI after discharge from hospital in Bangladesh. This thesis outlined a research program consisting of seven studies to fulfil the objective of this thesis. These findings explain the situation of people with SCI in Bangladesh after discharge from hospital. The findings from my studies will guide service providers including health professionals to prioritise services and deliver the best possible care for people with SCI in Bangladesh and other LMICs. The key findings and results of my studies are:

- People with SCI in Bangladesh suffer serious health complications after discharge. The most common complications are pressure ulcers, urinary tract infections, pain, depression and respiratory problems.
- There is poor survival at five-years following SCI in Bangladesh. The most common causes of death are secondary complications.
- It is possible to predict those with SCI who are at high risk of dying five years post-discharge. The predictors are ability to walk at discharge and age.
- Loss of employment after SCI causes extreme poverty for people with SCI and their families.
- Our model of care which included regular telephone calls and home visits was delivered successfully over a period of two years as stipulated in the protocol.
- The process evaluation of the CIVIC trial demonstrated that, the community-based intervention was highly valued by participants and healthcare providers. For example, participants stated that regular phone calls and home visits were useful for them in preventing their health complications and alleviating social isolation.
- The CIVIC trial indicates that regular contact with participants over the telephone does not reduce complications and mortality for people with SCI after they are discharged from hospital.

10.2 A summary of each study

10.2.1 The Cohort study

Study one (Chapter 3)

The first aim of the study was to determine five-year survival after discharge from hospital in Bangladesh. The second aim was to develop a prediction model to identify people at risk of death following hospital discharge. There were three main findings from this study. First, the five-year survival was 78% (95% CI, 74% to 82%). Second, there was a lower survival for people who were wheelchair-dependent at discharge: survival in this sub cohort was 69% (95% CI, 62% to 75%). Third, a simplemodel predicted survival as a function of age and mode of mobility at discharge (wheelchair-dependent or ambulant). The model shows that the odds of dying increased by a factor of 1.6 (95% CI, 1.3 to 2.0) with every decade of age and by a factor of 12.6 (95% CI, 4.8 to 32.9) if wheelchair-dependent. The model had good calibration and discrimination.This model could help clinicians to identify people with SCI who are at high risk of death following discharge but it needs to be externally validated before widely implemented.

Study two (Chapter 4)

The aim of the study was to determine health status, quality of life and socioeconomic situation of people with SCI sixyears after discharge from a hospital in Bangladesh. There were four main findings from this study. Firstly, the most common secondary complication was pressure ulcers. Fourteen percent of the cohort and 23% of those who used wheelchairs had pressure ulcers at the time of interview. Secondly, the QoL of people with SCI who are living in Bangladesh is not as low as one may anticipate, although the score from the SF 12 indicated more problems in the physical health domain (median 44; IQR 40

to 51) than the mental health domain (median 54, IQR 49 to 57). Thirdly, many participantsexperienced depression with a median (IQR) CESD-R total scores of 7 (4 to 13). Fourthly, participants experienced low levels of participation with a median (IQR) WHODAS 2.0 score of 12 (6 to 17). Fifthly, there were still many people with SCI unemployed (44%) and suffering financial hardship even six years after injury.For example, 65% were living below the poverty line with 50% of participants without any income each month (IQR, $US 0 to 91).

10.2.2 The CIVIC trial

Study three (Chapter 5)

The aim of this study was to develop a statistical plan for the CIVIC trial. The plan for the primary effectiveness analysis was to compare time to death from any cause between the two groups. Kaplan-Meier survival curves were to be used to compare survival between the two groups using the two tailed log-rank test. This study also described our plan for dealing with missing data. Participants' data were to be censored at the last time they were known to be alive.

Study four (Chapter 6)

The aim of this study was to develop a protocol for the process evaluation of the CIVIC trial. This study was valuable to guide the process evaluation of the CIVIC trial. This study explained the theoretical framework recommended by the Medical Research Council's guidance on process evaluations of complex interventions. This study outlined the method that was to be used for the process evaluation of the CIVIC trial based on the Realist and Reach, Effectiveness, Adoption, Implementation and Maintenance frameworks.

Study five (Chapter 7)

The aim of this study was to determine the degree of impoverishment of people with SCI and their families in Bangladesh caused by loss of work-related income following injury. The results of this study showed that people with SCI become unemployed after SCI and they consequently suffer severe impoverishment. The impoverishment does not affect only the person with the SCI but also his/her families. This study showed 74% of participants were the main income earners for their combined families. The median (IQR) family size was 5 (4 to 6) people. Prior to injury, participants' median (IQR) monthly income was $US 106 ($US 60 to $US 180) per person and family members' income was $US 30 ($US 19 to $US 48) per person. After injury, once the participants' incomes were removed, the median (IQR) income of each family member dropped to $US 0 ($US 0 to $US 18) placing 91% of families below the extreme poverty line of $US 37.50 per person per month (equivalent to $US 1.25 per day). Future research could try to determine the causal links between poverty and secondary complications after SCI in Bangladesh and other LMICs. The ideal study design for this would be longitudinal cohort studies using a representative sample. It would be important that data collection and the analyses were driven by a theoretical model that could be articulated in a Directed Acyclic Graph (DAGitty software could be used for this purpose)[71].

Study six (Chapter 8)

The aim of this study was to examine the delivery of the intervention of the CIVIC trial. Particularly, this study determined how the interventionwas delivered and the perceptions of participants and healthcare professionalsabout the intervention. This study suggests that, the intervention of the CIVIC trial was delivered as intended and the participants and

healthcare professionals valued the intervention. This study also found that people with SCI in Bangladesh face many problems that affect their lives after SCI. These problems may be too big to be addressed by the CIVIC intervention, explaining the failure of the CIVIC trial to prevent premature deaths.

Study seven (Chapter 9)

The aim of the study was to determine the effectiveness of our model of community-based follow-upto prevent serious complications and premature death following SCI in Bangladesh. This study is the first RCT of any type of intervention designed to support people with SCI post-discharge in Bangladesh or any other LMICs. The primary outcome was all-cause mortality. The secondary outcomes were burden of complications, prevalence and severity of pressure ulcers, depression, QoL, independence and participation. There was no loss to follow-up. The incidence of death was nearly identical in both groups (control and experimental). At twoyears 15/204 (7·4%) of 204 participants in the intervention group and 16/206 (7·8%) participants in the control group had died. The unadjusted hazard ratio was 0·93 (95% CI, 0·46 to 1·89; p value from the log rank test 0·85). None of the sensitivity analyses demonstrated clinically important or statistically significant effects on survival. There were no statistically significant or clinically important differences between-groups for any of the binary or continuous secondary outcomes. These results indicate no benefit of our model of community-based follow-up to reduce premature mortality for people with SCI after they are discharged from hospital. However, the intervention does not cause harm and participants reported benefits that were not captured in the outcome measures. Given there may be benefits of the model of care not captured in thestudy, and given the lack of other options, it may be reasonable for healthcare providers to consider providing this type

of care particularly as the results of the process evaluation suggest that it may reduce people's sense of social isolation.

10.3 Facilitators and barrier to conducting high-quality research in Bangladesh

The studies presented in this thesis were conducted in Bangladesh. There are numerous facilitators for conducting high-quality research in Bangladesh. However, there are also some barriers. A few facilitators and barriers that I experienced during my PhD are briefly described below.

10.3.1 Facilitators

The main facilitator enabling research in a country like Bangladesh is the low cost of labour. Consequently, money sourced in a country like Australia can go a long way. We were fortunate that we received a research grant from the National Health and Medical Research Council in Australia. This money was essential for enabling us to conduct the studies presented in this thesis. It funded staff in Bangladesh to manage the site, recruit participants,provide the interventions, and conduct the assessments The NHMRC funding also enabled us to employ staff at George India to oversee and manage the trial, as well as provide the site monitoring.

The other main facilitator to conducting research in Bangladesh is access to large numbers of potential and highly co-operative participants. This enabled me to recruit to the CIVIC trial in a timely way. Importantly, no-one withdrew from the CIVIC trial and all participants largely complied with the study protocol. The same surprising level of co-operation and follow-up is seen in other studies conducted in LMICs [11, 131] and may be due to several

factors. Firstly, participants may havehadstrong beliefs about the benefits of the interventions which encouraged them to comply. Secondly, cultural values and beliefs may have prompted participants to participate in the study and adhere to everything asked of them. For example, people in Bangladesh have a lot of respect for healthcare professionals and they are highly trusting of them and their advice. In addition, people in Bangladesh are rarely asked to participate in research. All of these factors may have meant that our participants were more willing to be part of research than their counterparts in a country like Australia. Most importantly, we were able to achieve high follow-up rates because participants lived in rural areas of Bangladesh and rarely moved to new residences. This enabled us to easily find them for follow-up assessments.

10.3.2 Barriers

The home visits that were part of the CIVIC trial were very challenging because transportation in Bangladesh is unreliable and uncomfortable. Staff often had to make five different connections on public transport to reach participants' homes and needed to use many different modes of transport. For example, to get to some participants'homes staff needed to catch a rickshaw, bus, ferry, van and motorbike, and then walk up to 5 kilometres across fields. This was very time consuming and difficult when the weather was very hot or rainy. Often one visit required two-days travel.

Another barrier I initially faced was identifying and then upskilling staff to run the CIVIC trial in Bangladesh. There were not many staff at CRP or in Bangladesh who possessed the necessary knowledge and skills to manage a large trial. Hence, they required a lot of training both in clinical management of people with SCI and trial management. Future trials need to

consider this issue very carefully because well-trained and supported staff are essential to the successful completion of trials such as the CIVIC trial. Nonetheless, the successful completion of the CIVIC trial proves that it is achievable.

Those involved in the CIVIC trial spoke 6 different languages betweenthem although English was the language in common to all. Nonetheless, it was sometimes difficult for staff from Bangladesh to effectively communicate in English. Therefore, extra care needed to be taken to avoid any misunderstandings. This was more of a problem at the start of the trial and improved as time went along. However, this should be a major consideration for others contemplating a similar type of study. It requires a lot of work and patience to ensure everyone understands each other.

Whilst the medical records were generally very good, I also found that sometimes they were incomplete. For example, I found that the ASIAImpairment Scale grades (collected as part of the International Standards for the Neurological Classification of People with SCI) collected for patients at the time of discharge were not always reliable. For this reason, I did not use these data for my cohort study but rather I relied on asking participantswhether they did or did not use a wheelchair at discharge. I reasoned that this was probably more reliable than using the ASIA Impairment Scale grades from the medical records. I did not have this same problem with the CIVIC trial because all data were collected prospectively, and staff received extensive training onthe International Standards for Neurological Classification of SCI. In addition, staff were required to conduct many supervised assessments before they started collecting data as part of the trial and their subsequent assessments were then monitored. This ensured that I could be confident that the data were accurate.

I used numerous outcome measurements that comprised questionnaires translated into Bangla. These were used to assess health and QoL, socioeconomic conditions and secondary complications after SCI. Most of our questionnaires were validated and used in other types of patients in Bangladesh however some of them had not been used for people with SCI before [112]. Therefore, I was not always confident that they were capturing the constructs they were designed to measure. I had these doubts because participants did not score as low as one might expect for people with SCI in LMICs on outcomes such as the SF12, CESD-R and WHODAS 2.0. An example is question 17 of the CESD-R which asks participant whether they have had "*crying spells*". In the Bangladesh context it would be most unusual for people, particularly men, to cry irrespective of their levels of depression. A study has also indicated that men (even from countries other than Bangladesh) are unlikely to respond to this question in the same way as women [109]. Another example can be seen in one of the questions from the SF12 asking participants if they have "*accomplished less than they would like*". Eighty-five percent of participants in mycohort study answered "*no*" in this question. This implies only a small number of participants accomplished less than they would like and most of them accomplished as much as they would like. The responses seem surprising and indicate a problem with the question because most of the participants were home bound and not able get out for work or for any purposeful activities due to social and environmental barriers. Similarity, participants had lower scores on the WHODAS 2.0 compared to other studies conducted in HICs and LMICs [115, 132] (where a lower score indicates higher levels of participation). This also seems surprising given the barriers to participation in Bangladesh. Some of these issues with the questionnaires require cautious

interpretation. Future research is needed to ensure that all questions are culturally appropriate and fully understood by a variety of culturally homogenous people[109].

10.4 Strengths and limitations of thestudies

10.4.1 Strengths:

The strengths of my studies were:

(I) **I recruited a representative sample for both my cohort study and clinical trial.** The cohort study recruited everyone with SCI who was discharged in 2011 from CRP. Similarly, I recruited a consecutive series of people with SCI who were recently discharged from CRP into the CIVIC trial. I managed to recruit 410 from 509 potentially eligible patients; equivalent to 74% of potentially eligible people. This indicated that my results were generalisable to most patients likely to be discharged from CRP.

(II) **The CIVIC trial adhered to all the widely recommended standards to conduct high-quality trials**. For example, prior to commencing the trial, a very detailed trial protocol was developed, and the trial conformed to International Conference on Harmonisation-Good Clinical Practicestandards. All the conditions of my trial were largely adhered to without any protocol violations recorded. In addition, prior to the completion of the trial, I published my study protocol and the statistical plan. These are important for transparency.

10.4.2 Limitations

The limitations of my studies were:

(I) **The results of my cohort study only reflect those discharged from CRP**: one hospital in Bangladesh. This is a potential limitation because it affects generalisability of the results. Unlike HICs, people with SCI in LMICs do not always get admitted to hospitals after SCI. Many stay in their homes and seek other treatments. However, there are no reliable data to indicate how many people with SCI never get to hospital. Given Bangladesh has a population of 163 million and in many other countries, the incidence of SCI is between 10 and 83 permillion[6, 133, 134], my best estimate is that between 2,400 and 12,800 people per year sustain a SCI in Bangladesh. Centre for the Rehabilitation of the Paralysed typically treats 400 people per year. Therefore between 2,000 and 12,400 people with SCI never make it to CRP. We do not know their typical outcomes, but presumably they would be worse than the outcomes of patients admitted to CRP. Therefore, the participants in my cohort study may not reflect everyone with a SCI in Bangladesh but rather those likely to do better than most.

(II) **I relied on family members to provide the date of death of loved ones**. This may have introduced error. I needed to do this because there is no death registry in Bangladesh. Another limitation of my cohort study was that I had to rely on retrospectively collected data for my candidate predictors. Consequently, I was limited by the data available in the medical records. I used type of lesion, mobility at discharge, gender, age and cause of SCI because I had these data and because I anticipated that they would be strong predictors (which some of them

were). However, if I could have selected more available candidate predictors and collected the data prospectively, I might have been able to develop an even better prediction model. For example, it would have been interesting to include education, history of pressure ulcers and place of residence (rural or urban) in my prediction model. These factors may be strong predictors of survival.

(III) **The intervention could have been delivered better in the early days**. The intervention for the CIVIC trial was provided according to the study protocol but I felt that staff learnt with time how to effectively deliver the intervention and it could have been delivered better from the beginning. For instance, at the beginning, when staff telephoned participants, they tended to just use the checklist. However, as time went on, they got better at speaking to the participants over the telephone and became more comfortable at using some of the counselling techniques they had been taught. Initially, we had hoped that staff would use motivational interviewing techniques. Staff were trained in these techniques. However, the principles did not transfer well to the Bangladeshi culture. Staff tried to use some aspects of motivational interviewing with varying degrees of success. Motivational interviewing is advocated because it is client-centred counselling and it helps people to resolve contradictory feelings. Motivational interviewing provides internal motivation to encourage people to change their behaviour. It is very important for people with SCI to change behaviour to achieve good health outcomes and to prevent health-related secondary complications. However, more work needs to be done in countries like Bangladesh to see if these principles are transferable.

10.5 Suggestions for future research

There are still many unanswered questions about QoL and survival following SCI in Bangladesh. For example, we are yet to fully understand the best model of care to support people with SCI following discharge. I have three key recommendations for future research. They are:

(I) Design outcome measures better able to capture QoL in the Bangladeshi context: It is ideal to measure QoL for people with SCI with appropriate measurement scales. We used the measures available and used extensively in this field, but we need to reviewthe measures to ascertain whether these measures are appropriate for a LMIC like Bangladesh. For instance, I used the SF12 Bangla version to measure QoL, however some of the questions may not be suitable in the Bangladesh context. In addition, this outcome measure (SF12) relies on a standard algorithm developed on the US general population adjusted for age and gender. I recommend reviewing the questions and examining the reliability and validity of the SF12 for people with SCI in Bangladesh and other LMICs. In addition, a careful review of the CESD-R and WHODAS 2.0 for people with SCI in Bangladesh is also necessary to ensure its appropriateness. Future research could also investigate the validity and reliability of the Bangla version of the CESD-R and WHODAS 2.0.

(II) Conduct studies involving people from hospitals throughout Bangladesh other than CRP: The participants from my studies were identified and recruited from only one hospital in Bangladesh, namely CRP. Many people with SCI get admitted to other hospitals in Bangladesh, but we do not know the precise numbers as we

do not have the data. We also do not know if those people that do not come to CRP are the same as those that do. Future studies could be directed at some of these issues. Firstly, attention could be directed at obtaining accurate estimates of the incidence of SCI in Bangladesh by conducting a population-based study. Secondly, studies looking at survival following discharge could include a more representative sample than just those discharged from CRP. Thirdly, our CIVIC trial could be repeated with people from all hospitals, not just those from CRP, to increase generalisability. Of course, all these studies would pose many logistical problems and would be costly to conduct.

(III) Externally validateour prediction model:I used a mixed prospective-retrospective study design to predict mortality. My model used available data as predictors. I found that age and mobility are good predictors of death for people with SCI in Bangladesh at five years post-discharge. This model had good calibration and discrimination. However, external validation of this model for people with SCI in other LMICs will provide valuable information about the sensitivity and generalisability of our prediction model. In addition, it is possible that this prediction model could be improved with the inclusion of other predictors.

10.6 Implications for clinical practice

There are two main implications of my body of work for clinical practice. They are:

(I) The prediction model could be used to prioritise care post-discharge to those most likely to die: The prediction model developed from my cohort study now

needs to be externally validated; however, initial results indicate that this simple prediction model could be used by clinicians in Bangladesh and other LMICs to priorities care post-discharge. Similar systems of prioritising care post-discharge are already used in countries like Afghanistan but it is not clear if these systems are based on good evidence[135]. My model could help countries like this further refine their systems to ensure that scarce resources are directed where they are most needed.

(II) The findings of the CIVIC trial can inform decisions about whether community-based support post-discharge is a worthwhile use of limited resources: It is very clear from the results of the CIVIC trial thatregular telephone-based support and a few home visits donot prevent serious complications and premature death in people with SCI in Bangladesh. The findings of this trial need to be disseminated to people with SCI, policy makers and service providers. These people need to consider carefully whether this type of intervention should be rolled out in their communities. Clearly, I have shown that it won't save lives or reduce complications. However, there may be other benefits that were not captured in my trial and perhaps it is premature to argue that this type of service should not be provided to people who have few other options. In addition, it is possible the intervention is effective if provided to people in different circumstances. For example, perhaps it is effective in people who do not receive any type of rehabilitation post injury. So it may be premature to assume that this model of care is ineffective for all. However, on the other hand, this model of care takes money and resources that may be directed elsewhere. These are all difficult

decisions with no simple answers but it is clear that we need more high-quality research directed at finding solutions. The way forward may be to identify some of the research gaps in primary health care delivery systems in Bangladesh. In addition, qualitative work could be directed at further exploring those who may benefit from my model of care[136, 137]. This work needs to be followed-up by high quality RCTs.

10.7 Other general recommendations

From my body of work, there are two general recommendations that are not directly related to my studies but were reoccurring themes worthy of comment. They are:

(I) **There is a need to improve vocational training and employment opportunities for people with SCI to reduce the financial strain on them and their families:** Unemployment following SCI is a serious challenge for people with SCI living in LMICs. Vocational training needs to be strengthened to create employment opportunities for them and their families. A small amount of microcredit support and/or interest free loans could play an important role in helping people with SCI set up businesses. In addition, public-private partnerships could be trialled to improve the employment and financial situation of people with SCI living in LMICs. Lastly and most importantly, the government needs to ensure that those with SCI are provided with financial protection embedded within an appropriatesocial support system.

(II) **There is a need to strengthen primary health care facilities so they can better manage people with SCI in their communities:** People with SCI require access to health care services (preferably primary health care services) that are close to

their homes. These services are needed to help them manage their health. In addition, people with SCI require access to rehabilitation post-discharge. This could also be provided through the primary health care services. However, the expansion of healthcare services to better serve people with SCI will not only require appropriate systematic planning to ensure they are staffed by appropriately skilled professionals but they will also require extensive coordination to ensure that they reach all individuals with SCI [138]. Scoping work is required to understand what is currently available in the various primary health care settings. Then work is required to ensure that these services are coordinated and patient-centred [139]. There are no accurate data on how much moneyisspentby the government nor how much money is spent by individuals on primary health care in Bangladesh [140].Scoping work could look at how accurate data and information systems could be improved, and how primary health care system could be strengthened in Bangladesh.

10.8 Conclusions

The results of my cohort study demonstrated that people with SCI in Bangladesh have a low QoL at six years post-discharge although their QoL is not as low as one might expected for people with SCI living in LMICs. This study further indicated that people with SCI in Bangladesh suffer many secondary complications with pressure ulcers being the most common complication. Muscle pain and spasm, bowel and bladder problems and sexual problems are also very common in people with SCI. The five-year survival was poor although it was comparable to survival in other LMICs. I was able to develop a prediction model to identify those at high risk of dying following discharge. The prediction model suggests that

age and mobility are good predictors of dying following discharge. This prediction model now needs to be externally validated; however, initial results indicate that it can be used by clinicians to identify people with SCI living in Bangladesh and other LMICs who are at high risk of death soon after discharge. This model will be useful for ensuring resources are directed at those most in need. The methodology we used for the cohort study could beused by other researchers interested in determining survival following discharge. They could try to replicate and hence validate our results in their own independent research.

Similarly, the results of my CIVIC trial will be useful for guiding future practice in LMICs. The CIVIC trial demonstrated that a low-cost community-based model of care was not effective for preventing serious complications and reducing premature mortality for people with SCI in Bangladesh. Moreover, the results of my cross-sectional study from the baseline data of the CIVIC trial indicated people with SCI and their families are living in extreme poverty largely due to the loss of work.

My studies provide the first reliable information about the lives of people with SCI and their families in Bangladesh and provide one of the first attempts at finding a solution. While the primary results of the CIVIC trial did not indicate that our model of care saved lives, they are nonetheless important because they help guide the search for future solutions to the problems of living with SCI in Bangladesh and other LMICs.

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Appendix A: Published pilot study forthe CIVIC trial

(publication related to the CIVIC trial but not completed as part of my PhD candidature)

Original Article

CLINICAL REHABILITATION

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A pilot randomised trial of community-based care following discharge from hospital with a recent spinal cord injury in Bangladesh

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Abstract

Objectives: To explore the feasibility of conducting a full trial designed to determine the effectiveness of a model of community-based care for people with spinal cord injury in Bangladesh.
Study Design: A pilot randomised trial.
Setting: Community, Bangladesh.
Subjects: Participants were 30 people with recent spinal cord injury who were wheelchair-dependent and soon to be discharged from hospital.
Intervention: Participants randomised to the intervention group received a package of care involving regular telephone contact and three home visits over two years. Participants randomised to the control group received usual care consisting of a telephone call and an optional home visit.
Main measures: Participants were assessed at baseline and two years after randomization. The primary outcome was mortality and secondary outcomes were measures of complications, depression, participation and quality of life.
Results: A total of 24 participants had a complete spinal cord injury and six participants had an incomplete spinal cord injury. Median (interquartile) age and time since injury at baseline were 31 years (24 to 36) and 7 months (4 to 13), respectively. Two participants, one in each group, died. Five participants had pressure ulcers at two years. There were no notable impediments to the conduct of the trial and no significant protocol violations. The phone calls and home visits were delivered according to the protocol 87% and 100% of the time, respectively. Follow-up data were 99% complete.
Conclusion: This pilot trial demonstrates the feasibility of a full clinical trial of 410 participants, which has recently commenced.
Sponsorship: University of Sydney, Australia.

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Spinal cord injuries, complications, mortality, community-based care

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Introduction

In low- and middle-income countries, people who initially survive spinal cord injury subsequently face the significant challenge of surviving in the community following discharge from hospital.[1–7] We recently reported two-year outcomes of a cohort of 350 people discharged with spinal cord injury from a specialised hospital in Bangladesh: one in five of those who were wheelchair-dependent had died within two years of discharge (survival was 81%; 95% confidence interval (CI) 76% to 86%).[7] The primary cause of death was sepsis from pressure ulcers.[8] However, other complications also threaten survival and quality of life.[9]

Members of our team working in Bangladesh have proposed a model of community-based care designed to reduce mortality and improve quality of life following discharge with spinal cord injury. The model is particularly suited for use in low- and middle-income countries. The model of care involves regular telephone-based monitoring and support and a small number of home visits. Community-based models of care have been widely advocated for people with spinal cord injury and other physical disabilities in low- and middle-income countries.[10,11] However, there is very little robust data to demonstrate their effectiveness or cost-effectiveness.[12]

We conducted a pilot trial to determine the feasibility of conducting a large clinical trial to test the effectiveness and cost-effectiveness for our proposed model of community-based support for people recently discharged from hospital with spinal cord injury in Bangladesh. The aims of this pilot trial were to test the assessment procedures, ensure recruitment targets could be met, refine the intervention and determine whether it is possible to obtain high rates of follow-up at two years.

Method

A single-blind randomised controlled pilot trial was undertaken to determine the feasibility of a full trial. The 30 participants were randomised between November 2013 and February 2014, and the two-year follow-up assessments were completed between December 2015 and February 2016. The trial was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12613001137785). All applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed.

A total of 30 people with recent spinal cord injury who were wheelchair dependent and about to be discharged home from the Centre for the Rehabilitation of the Paralysed in Bangladesh were invited to participate. To be included in the trial, participants had to be at least 18 years of age, have sustained a traumatic or non-traumatic spinal cord injury within the last two years and require a wheelchair for daily mobility. Potential participants were excluded if they were planning to move to another country or were being transferred to another hospital for medical care.

A random allocation schedule was generated prior to commencement of the trial by a person in Australia not involved in the recruitment of participants. Allocation was in randomly permuted blocks within two stratum (paraplegia/tetraplegia), using the 'ralloc' command in Stata.[13] Once a participant was screened, provided consent and completed the initial assessments, trial staff in Bangladesh were notified by email of the participant's allocation. The participant was considered to have entered the trial once the notification was sent.

Participants allocated to the intervention group were telephoned by a healthcare provider every two weeks in the first year following discharge and then every month in the second year. Participants were telephoned more frequently if they had a pressure ulcer or any other complication. Participants who developed pressure ulcers or other complications were encouraged to telephone the healthcare provider as required. In addition, participants were

visited in their homes; twice in the first year and once in the second year after discharge.

Every time the healthcare provider made contact with a participant, the participant was questioned about complications (or examined for complications if the contact was during a home visits), and provided with advice and support. The healthcare provider acted as case coordinator and advocate, helping participants source local support as necessary. The healthcare provider also provided advice and support to family and local community members. If the participant developed serious complications, then the healthcare provider attempted to find the participant appropriate medical and nursing care or hospitalisation. Up to AUS$80 per participant was used to purchase care or equipment over the two years; these funds were not given directly to participants. Standardised forms were used to record the problems identified and advice or assistance provided.

The healthcare provider responsible for providing the interventions for the experimental participants was a physiotherapist with three years clinical experience in spinal cord injuries. This person received additional training in relevant aspects of care (such as prevention and treatment of pressure ulcers and depression, and management of bladder and bowel problems) for people with spinal cord injuries.

Participants allocated to the control group continued to receive the care typically provided for patients discharged from the Centre for the Rehabilitation of the Paralysed. Some participants were telephoned on one occasion within the first few months of discharge and some deemed at high risk of complications were visited at home on one occasion. The Centre for the Rehabilitation of the Paralysed also provided telephone advice to control participants who contacted the Centre.

Participants in both groups were assessed at the Centre for the Rehabilitation of the Paralysed just prior to discharge and again in participants' homes two years later. Assessments were carried out by trained, blinded assessors. The success of blinding (patterns of belief about allocations of participants in the intervention and control groups) was monitored. The primary outcome was all-cause mortality. Bangladesh does not have a death registry, so the date of death was confirmed by the blinded assessors after interviewing next of kin at two years.

Details of the secondary outcomes are provided in our trial protocol.[14] In brief, secondary outcomes were as follows.

- *Burden of complications* measured with the Spinal Cord Injury Secondary Conditions Scale.[15]
- *Presence of pressure ulcers* measured on a dichotomise 'yes/no' scale.
- *Depression* measured with the Center for Epidemiologic Studies Depression Scale revised version.[16–18]
- *Health-Related Quality of Life* measured with the SF12.[19]
- *Severity of pressure ulcers* measured with the Pressure Ulcer Scale for Healing version 3.[20,21]
- *Independence* measured with the Spinal Cord Independence Measure Self Report.[20–23]
- *Participation* measured with the eight participation items of the World Health Organization Disability Assessment Schedule v2 36-item self-report questionnaire.[24]

In addition, at the two year assessment, participants were asked three questions about how often in the last week they got out of bed, got out of the house and engaged in work.

Data were analysed descriptively using Stata v13. Estimates of treatment effect are not reported because the pilot trial was designed to determine feasibility, not effectiveness. The sample size was not sufficient to provide meaningful estimates of the effects of the intervention.

Results

A total of 30 people were randomised. The two groups were similar at baseline (Tables 1 and 2). No participant withdrew from the trial and all were assessed (or in the case of those who died, accounted for) at two years (Figure 1).

The registered protocol was followed with one important exception. Initially it was intended that the first 30 participants would be randomised as

Table 1. Characteristics of participants at baseline ($n = 15$ for both groups). Data are medians (interquartile range) and counts.

	Control group	Intervention group
Age (years)	34 (23 to 36)	29 (24 to 35)
Time (months) since injury	7.0 (3.8 to 13.6)	5.8 (3.8 to 12.5)
Male: female participants, *n*	13:2	13:2
Neurological level, *n*		
C5 to C8	6	5
T1 to T7	0	1
T8 to T12	5	6
L1 to L5	4	3
ASIA impairment scale, *n*		
A	12	12
B	1	0
C	2	2
D	0	1

ASIA: American Spinal Injury Association.

Table 2. Results of baseline and two year assessments. Data are mean (SD) for 30 participants at baseline and 28 survivors at two years, except where indicated.

	Baseline		Two years	
	Control ($n = 15$)	Intervention ($n = 15$)	Control ($n = 14$)	Intervention ($n = 14$)
Died, *n*	—	—	1	1
Spinal Cord Injury Secondary Conditions Scale, /49 points	3.6 (2.6)	4.7 (2.7)	5.0 (3.4)	4.1 (2.2)
Existence of pressure ulcer, *n*	0	0	2	3
Pressure Ulcer Scale, /17 points[a]	—	—	13.0 (5.7)	10.7 (1.2)
CES Depression Scale, /60 points	30.7 (9.6)	28.8 (9.6)	30.1 (10.0)	29.7 (9.3)
SF12 Physical subcomponent, /standardised units	35.7 (4.6)	36.1 (3.7)	38.4 (3.5)	39.5 (3.6)
SF12 Mental subcomponent, /standardised units	40.9 (4.8)	38.8[b] (5.8)	37.7 (10.9)	38.8 (13.1)
Spinal Cord Independence Measure, /100 points	46.6 (19.1)	45.8 (15.9)	53.0 (16.7)	50.5 (21.3)
WHODAS, /40 points	14.3 (2.1)	14.6 (2.4)	18.3 (3.4)	19.0 (6.0)
Out of bed, number of days in past week	—	—	5.8 (2.0)	6.1 (2.0)
Out of house, number of days in past week	—	—	4.0 (3.2)	4.0 (3.4)
Work, number of days in past week	—	—	2.5 (3.5)	1.5 (3.0)

[a]Pressure Ulcer Scale scores are only for the five participants who had a pressure ulcer.
[b]One participant did not answer one question (Q5a). A response of 'no' was used in the analysis for this participant to this question because this was the most frequent response.
CES: Centre for Epidemiologic Studies; WHODAS: World Health Organization Disability Assessment Schedule; SF12: SF12 Health Survey.

part of a full trial of 410 participants (i.e. the first 30 participants would constitute an 'internal' pilot trial).[25,26] Subsequently the decision was made to terminate the trial at 30 participants and regard it as an 'external' pilot trial rather than include those 30 participants in the full trial of 410 participants. This decision was made without knowledge of interim results from the first 30 participants.

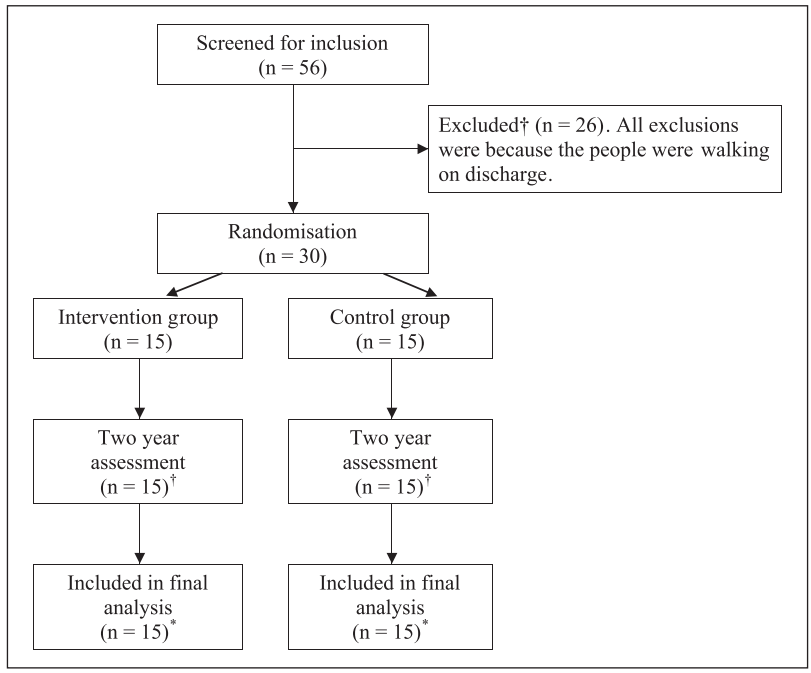

Figure 1. Flow of participants through the trial.
†14 potentially eligible participants were not screened during the recruitment period because the trial staff member responsible for recruitment was on leave for a short period without replacement.
*Includes the two participants who died before the two-year assessment.

The protocol dictated that participants in the intervention group receive three home visits, and be telephoned fortnightly in the first year and monthly in the second year (i.e. 38 phone calls in total). In practice, all participants in the intervention group received three home visits, and they received a median (interquartile range (IQR)) of 33 (31 to 33) phone calls (excluding the participant who died). The protocol also dictated that participants be re-assessed two years from randomization. In practice they were re-assessed a median of two years (IQR 1.9 to 2.1 years) from randomization. The only missing datum was the response from one participant to one question in the SF12 at baseline. This question required a 'yes' or 'no' response. The missing data point was imputed with the modal response. There were no incidences of unblinding of outcome assessments.

Two participants, one from each group, had died by two years. The baseline and follow-up data for the secondary outcomes are shown in Table 2.

Adverse event data were available for participants in the intervention group but not for participants in the control group. Participants in the intervention group experienced four serious adverse events, including one death and three hospitalisations for major pressure ulcers.

Discussion

Two participants had died by the two-year assessment. This mortality rate (7%; 95% confidence interval (CI) 2 to 21) is lower than was observed in our earlier cohort study of 350 participants (19%, 95% CI 14 to 24).[7] The lower rate observed here could be due to the intervention or it could reflect the very imprecise estimate of mortality afforded by the pilot sample of 30 participants.

The validity of the mortality data depends critically on being able to account for outcomes of all participants at two years. This required that participants or their families be located two years after

discharge from hospital. We were initially concerned that this might be a problem, particularly for the control participants who we did not contact over the two-year period. We considered occasionally telephoning the control participants throughout the trial to minimise difficulty locating participants at the time of the follow-up assessment. However we decided not to do that because the telephone contacts could have caused contamination (i.e. could have caused participants in the control group to have received some of the intervention). It was therefore reassuring that we were able to locate all participants, including all of those allocated to the control group, at two years. We had similar success finding participants two years after discharge in our earlier cohort study.[7] In that trial we were able to locate and determine outcomes for 97% of 350 participants. Our success in following up participants is in contrast to the low follow-up rates often reported in studies conducted in high-income countries.

As expected, pressure ulcers were a major problem. At two years, one participant had died from a pressure ulcer, five participants currently had a pressure ulcer, three participants had been hospitalised for serious pressure ulcers and six participants indicated that pressure ulcers had been either a moderate or severe problem in the preceding three months. The problems of pressure ulcers in low- and middle-income countries are widely documented, although few studies provide precise and accurate estimates of the scale of the problem. Clearly, better strategies are needed to address the problems of pressure ulcers after discharge from hospital with a spinal cord injury in low- and middle-income countries. The intervention administered in this trial had a major focus on preventing and treating pressure ulcers: Trial staff routinely asked participants about their skin and reminded participants to persist with strategies for prevention of pressure ulcers. At the first indication of a pressure ulcer, participants were provided with advice, and in three cases were encouraged to return to hospital. The full trial that is currently underway will indicate whether these strategies reduce mortality from pressure ulcers.

The Spinal Cord Injury Secondary Conditions Scale was included as a secondary outcome measure to give an indication of the burden of complications. The burden of complications at two years was measured rather than the incidence of complications over the two-year study period to avoid the need for close and ongoing monitoring of control participants. This outcome measure was reasonably easy for participants and assessors to use, although there are some ambiguities in the questions and some culturally inappropriate questions that caused problems. For example, one question asks participants to indicate whether they had experienced 'sexual dysfunction'. Often participants stated that they had 'not experienced' sexual dysfunction, but it was frequently not clear whether this meant participants had not been sexually active, were satisfied with their sexual function or were not prepared to discuss their sexual experiences with the assessor.

Depression was assessed using the Center for Epidemiologic Studies Depression Scale. We chose to use this tool rather than the more commonly used measures of depression because it had previously been used in Bangladesh and was available in Bangla.[17,18] While studies have verified its usefulness for the Bangladesh context, we were not confident about the appropriateness of some of the statements that participants were asked to respond to. For example, participants did not always relate to statements such as 'I felt that people disliked me', 'I felt I was just as good as other people' and 'people were unfriendly'. It is possible that these perceptions are reflective of depression in some cultures but not others. Nonetheless the scale includes 20 statements, most of which reflected emotions and feelings that are universally associated with depression.

Often the biggest challenge of conducting a clinical trial is recruitment. However, we recruited 30 participants over a 14-week period, including a short period when the staff member responsible for recruitment was on leave with no replacement. This reassured us that we would be able to recruit 410 participants to the full trial in a timely way. We have now commenced the full trial and have randomised 150 participants over the first 10 months, a rate that exceeds our recruitment target. The successful recruitment rate reflects the large number

of patients moving through the Centre for the Rehabilitation of the Paralysed each year. It also reflects patients' willingness to be involved in the trial. Patients understand that if they are randomised to the control group, they will receive the care currently provided to patients discharged from the Centre for the Rehabilitation of the Paralysed. Alternatively, if randomised to the intervention group, they will receive ongoing support. Patients perceive there are few risks associated with participation in the trial and there is potential to benefit if allocated to the intervention group.

The model of community-based care used in this pilot trial involves regular telephone contact supplemented by three home visits over a two-year period. Effective provision of support relied on the healthcare provider's ability to develop a rapport with the participants, pick up problems at an early stage and provide appropriate advice and support. It also relied on participants' willingness to disclose and discuss their problems and adhere to the advice provided.

We were unsure about how successful we would be at maintaining regular telephone contact with participants, because even though we knew that there was a very high mobile phone penetration in Bangladesh, we also knew that people in Bangladesh regularly change their phone cards and phone numbers.[27] However, we took the contact details of many different family members and friends, and we educated participants about the need to keep us informed if they changed their phone numbers. If a participant did not have a mobile telephone, then often a family member or neighbour did. One way or another, trial staff were able to maintain contact with participants in the intervention group for the two-year period.

We were also initially concerned about the possibility that participants would decline to speak to the trial staff member when telephoned or visited, and that consequently there would be a high loss to follow-up. These concerns were based on our experiences of other trials involving regular interaction with trial staff over extended periods of time. However, we did not experience any of these problems. This may be because experimental participants enjoyed and valued the regular contact with the healthcare provider.

Many participants faced insurmountable life problems for which there were no clear solutions. For example, one participant developed a serious pressure ulcer, but he continued to get out of bed and sit on the pressure ulcer despite advice to the contrary. He was not being deliberately obstinate, but needed to get into his wheelchair so he could seek an income. If he did not, then he and his family faced a larger and more immediate problem than his pressure ulcer. These types of problems, which are prevalent in low, and middle-income countries, raise the question of whether participants' problems are too great to be resolved by telephone support. The full trial will provide an answer to this and related questions.

The intervention for the full trial has been further refined on the basis of what we have learnt from this pilot trial. For example, we are now placing a larger emphasis on the way trial staff speak and interact with patients. We are training trial staff to encourage patients to problem solve and to set their own goals. We are also training trial staff in interview techniques that allow patients to discuss their problems in a supportive environment. This approach is in contrast to the pilot trial, where the emphasis was primarily on monitoring for problems and providing education and advice.

The weakness of this pilot trial is the small sample size. However, the trial was not designed to determine the effectiveness of the intervention or to determine the sample size needed for the full trial. Rather, it was designed to determine feasibility. The power calculations for the full trial are based on our much larger cohort study, which was conducted at the same site and which provided precise estimates of expected survival in the control group at two years following discharge (81%, 95% CI 76 to 86).[3] The current pilot trial provides an independent estimate of two-year survival without intervention: one death from 15 control participants implies a two-year survival of 93%. This estimate is very imprecise (95% CI 70 to 99) because it is based on a very small sample size. Nonetheless it is consistent with the more precise estimate from our larger cohort study. We estimated that a sample size of 410 gives a better than 80% probability of detecting an increase in survival from 83% to 93% at two years with a

two-sided log-rank test, uniform follow-up time of two years, loss to follow-up in both groups of 15% at two years and alpha of 0.05. The current pilot trial suggests that loss to follow-up in the full trial may be less than the anticipated 15%.

If the full trial demonstrates the effectiveness of the intervention, policy makers will need to decide if the effects justify the cost of the intervention. For this reason, the full trial includes a cost-effectiveness analysis. The main cost associated with the intervention is the three home visits. While Bangladesh is a relatively small country, travel around the country is slow. This makes travel to participants' homes from a central location time consuming and costly. These costs could be reduced by having appropriately trained staff dispersed throughout Bangladesh or by upskilling community healthcare workers to support people with spinal cord injury. But it may be premature to consider how the intervention could be rolled out until there is clear evidence that the intervention is effective.

This pilot trial indicates it is feasible to conduct a large randomised controlled trial of the effectiveness of a community-based model of care following discharge from hospital with spinal cord injury in Bangladesh. The results of the full trial will have implications for other low- and middle-income countries and other types of disabilities. It is particularly important that models of community-based care are based on high-quality evidence in countries like Bangladesh, because health resources are very limited and need to be used wisely.

Clinical message

- It is difficult but possible to provide regular follow-up after discharge for people with spinal cord injuries in low- and middle-income countries.
- Mobile telephones and close family ties provide a way of supporting people with spinal cord injuries when discharged from hospitals in low- and middle-income countries.

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Declaration of conflicting interests

The authors declare no conflict of interest. The Centre for the Rehabilitation of the Paralysed and the University of Sydney did not influence the design of the trial or interpretation of the results in any way.

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Appendix B: Published protocol for the CIVIC trial

(publication related to the CIVIC trial but not completed as part of my PhD candidature)

BMJ Open

Community-based InterVentions to prevent serIous Complications (CIVIC) following spinal cord injury in Bangladesh: protocol of a randomised controlled trial

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ABSTRACT

Introduction: In low-income and middle-income countries, people with spinal cord injury (SCI) are vulnerable to life-threatening complications after they are discharged from hospital. The aim of this trial is to determine the effectiveness and cost-effectiveness of an inexpensive and sustainable model of community-based care designed to prevent and manage complications in people with SCI in Bangladesh.

Methods and analysis: A pragmatic randomised controlled trial will be undertaken. 410 wheelchair-dependent people with recent SCI will be randomised to Intervention and Control groups shortly after discharge from hospital. Participants in the Intervention group will receive regular telephone-based care and three home visits from a health professional over the 2 years after discharge. Participants in the Control group will receive standard care, which does not involve regular contact with health professionals. The primary outcome is all-cause mortality at 2 years. Recruitment started on 12 July 2015 and the trial is expected to take 5 years to complete.

Ethics and dissemination: Ethical approval was obtained from the Institutional Ethics Committee at the site in Bangladesh and from the University of Sydney, Australia. The study will be conducted in compliance with all stipulations of its protocol, the conditions of ethics committee approval, the NHMRC National Statement on Ethical Conduct in Human Research (2007), the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95) and the Bangladesh Guidance on Clinical Trial Inspection (2011). The results of the trial will be disseminated through publications in peer-reviewed scientific journals and presentations at scientific conferences.

Trial registration numbers: ACTRN12615000630516, U1111-1171-1876.

Strengths and limitations of this study

- This will be the first large, high-quality trial to determine the effect of post-hospital community-based care on mortality in people with spinal cord injury. It is also among the first randomised trials of community-based care for people with physical disabilities in low- or middle-income countries.
- The results of this trial will have implications for the development of inexpensive models of care for people with spinal cord injury and possibly also other causes of physical disability in low- and middle-income countries.
- The trial is being conducted from one specialised spinal cord injury unit in Bangladesh, which may not be representative of all people with spinal cord injury or hospitals in low-income and middle-income countries.

INTRODUCTION

The incidence of spinal cord injury (SCI) in low-income countries is four times that in high-income countries.[1–4] In most low-income countries, people who sustain a SCI are discharged home with little access to support services. Not surprisingly, they often then develop life-threatening complications. Many die within a few years of discharge.[5–11] We have recently shown that 19% of wheelchair-dependent patients discharged from a large SCI unit in Bangladesh die within 2 years of discharge.[11] The median (interquartile) age in this sample was 32 years (25–44) and the most common cause of death was sepsis due to pressure ulcers.[11–14] There are no directly comparable data from high-income countries but death

in the first 2 years following discharge in those <40 years of age is unusual.[15 16]

Pressure ulcers and most other complications of SCI can be prevented and treated through education and with simple, inexpensive home-based treatments, as outlined in numerous international clinical practice guidelines.[17–22] These include strategies such as the provision of foam overlays on beds, regular change in position, appropriate bladder drainage, high-fibre diet and good fluid intake. The key to successful prevention and treatment of complications is not costly or complex medical interventions, but rather, patient and family monitoring, education and support.[3 23] High-income countries have well-developed systems to provide community-based health services, especially in the period immediately after discharge, when patients are most vulnerable to complications. But it is not economically feasible to provide the same services in low-income countries. An inexpensive and sustainable model of community-based care is required.

The high incidence of serious but preventable complications following SCI in Bangladesh suggests that a suitable intervention could yield large health and social benefits at relatively little cost.[3] We have developed a low-cost, sustainable community-based model of care for people who have returned home after SCI. The model of care involves regular telephone-based monitoring and provision of ongoing education, support and advice, along with a limited home-based service. The service can be provided in the first 2 years following discharge, when patients are most vulnerable to complications. It is thought that if high-risk patients can be supported over the first 2 years, most will go on to learn self-help skills and will become competent at managing their disabilities.

Inexpensive, community-based models of care for people with physical disabilities in low-income and middle-income countries are widely advocated.[24 25] So it is surprising that there is very little robust data that demonstrate the effectiveness or cost-effectiveness of such interventions. Existing community-based models of care in low-income and middle-income countries are generally not based on rigorous evidence. A systematic and evidence-based approach to the provision of healthcare for the disabled is required.[26–29] In particular, a high-quality clinical trial is essential to provide unbiased and precise estimates of the effectiveness and cost-effectiveness of a sustainable model of community-based care for people with SCI.

Aim

The aim of the Community-based InterVentions to prevent serIous Complications (CIVIC) trial is to provide unbiased and precise estimates of the effectiveness and cost-effectiveness of a model of community-based care for wheelchair-dependent people with SCI who have been discharged from hospital in Bangladesh. The primary hypothesis is that the community-based model of care will be more effective than standard care in reducing all-cause mortality at 2 years. The secondary hypotheses are that the community-based model of care will be more effective than standard care in decreasing the burden of complications, decreasing the prevalence and severity of pressure ulcers, decreasing depression, improving quality of life, improving independence and increasing participation. In addition, it is hypothesised that the community-based model of care will be cost-effective from a health provider perspective.

METHODS AND ANALYSIS

Design

A pragmatic randomised controlled trial will be undertaken. The trial is investigator initiated. The protocol has been registered prospectively with the Australia New Zealand Clinical Trials Registry (ACTRN12615000630516).

Participants

The trial will have broad inclusion criteria in keeping with its pragmatic orientation. A person will be eligible to participate if he or she has sustained a traumatic or non-traumatic SCI within the last 2 years, is aged 15 years or over at the time of consent, is an inpatient at the Centre for the Rehabilitation of the Paralysed in Bangladesh, requires a wheelchair for mobility on a daily basis and is about to be discharged home. People will be excluded if they are planning to move to another country following discharge or if they are to be transferred to another hospital for medical care. Participants will be provided with trial information sheets. Trial staff will obtain written informed consent from all participants prior to inclusion in the trial.

Recruitment strategy and time frame

Four hundred and ten patients will be recruited prior to their discharge from the Centre for the Rehabilitation of the Paralysed. The Centre is a 100-bed spinal injury unit that admits 360 patients a year, making it one of the largest spinal injury units in the world.[30] We estimate that it will take 2 years to recruit the required sample based on data collected from admissions and discharges in 2011.[11]

Recruitment started on 12 July 2015. Fifty-three participants were randomised between that date and 22 October 2015.

Assignment of intervention

Randomisation is stratified by severity of injury (paraplegia or tetraplegia). The allocation schedule was computer generated by an Australian-based investigator (RH). The schedule is concealed from potential participants, trial staff and investigators, except one investigator (RH) and two India-based trial staff members not involved in recruitment. Randomisation will occur shortly after discharge from hospital. The site coordinator will contact the central randomisation unit by email, whereupon the

central randomisation unit will notify the site coordinator of treatment assignment. Eligible participants will be randomised to one of two groups: an Intervention group that will receive community-based care or a Control group that will receive standard care.

Interventions

Intervention group

Participants allocated to the Intervention group will receive telephone-based support and a limited number of home visits in the first 2 years following discharge. Community-based healthcare workers or healthcare professionals will contact participants by telephone fortnightly in the first year and monthly in the second year. During the call, participants will be screened for complications using purpose-designed forms. Specifically, the healthcare workers will screen participants for pressure ulcers, urinary tract infection, bowel impaction, bladder infection, depression, autonomic dysreflexia and respiratory complications. At the first indication of any of these complications, the healthcare workers will provide advice to participants and their families about management, and then closely monitor them by telephone until the complication is resolved. The healthcare workers will refer participants to local service providers where necessary and when possible. The advice will follow international clinical practice guidelines[17 18 20–22 31–34] appropriately modified for the Bangladesh context. Where available and appropriate, the camera and video facilities of smartphones will be used to help monitor a participant's condition. The healthcare workers will also provide ongoing education, support and advice over the telephone. They will reinforce self-help strategies important for preventing complications, minimising psychological stress and enhancing social engagement. They will also speak to and support participants' families.

On three occasions, the healthcare workers will also visit participants and their families in their homes. There will be two home visits in the first year and one home visit in the second year. At each home visit, the healthcare worker will assess the participant's home situation and provide advice as needed. For example, they will review cushions and mattresses used to prevent pressure ulcers, and provide advice on wound treatment, bladder and bowel management, and other aspects of ongoing care. Healthcare workers will seek solutions to mobility and self-care limitations. On the first home visit, the healthcare workers will also provide participants with a pictorial educational booklet specifically created for the trial. Participants will be provided with items of care such as wound dressings and urinary catheters if they cannot otherwise afford these items. The number of phone calls and home visits provided to the Intervention participants will be monitored.

Control group

Participants allocated to the Control group will receive the level of postdischarge care currently provided by the Centre for the Rehabilitation of the Paralysed. That is, a social worker may telephone participants once after discharge. In addition, participants with tetraplegia deemed at high risk of complications by the social worker may receive one home visit. The format of these telephone contacts and home visits will not be structured but will typically include a discussion around any problems since discharge.

Outcome measures

Outcomes will be measured at 2 years in participants' homes. Most outcomes will also be measured at baseline (ie, prior to randomisation while participants are still in hospital). Outcome data will be collected by blinded assessors. The success of blinding (patterns of belief about allocations of participants) will be monitored and reported. Extensive contact details for all participants will be collected at baseline to minimise loss to follow-up.

The primary outcome is all-cause mortality. Bangladesh does not have a death registry so the date of death will be confirmed by interviewing next of kin or carers at 2 years. Wherever possible, independent corroboration of the date of death will be obtained, for example, from local community leaders.[35]

The secondary outcome measures will be burden of complications, prevalence and severity of pressure ulcers, depression, quality of life, independence and participation. Questionnaires used to elicit self-reported outcomes will be administered in the Bangla language, under the guidance of the assessor. The details of each secondary outcome are as follows:

1. *The burden of complications* will be measured using the SCI Secondary Conditions Scale (SCI-SCS).[36 37] This is a 16-item scale. Each item is scored from 0 (did not experience the complication in the last 3 months) to 3 (significant or chronic problem over the past 3 months). The score for each item will be determined by the assessor after asking the participant any question deemed relevant and after physically examining the participant, if necessary. The scores will be summed to provide an overall score with a total possible score of 48, where 0 represents no complications and 48 represents severe complications over the past 3 months. Incidence of complications over the 2-year period after discharge will not be measured because doing so would require ongoing monitoring of participants in the Control group, which is not feasible and could contaminate the intervention.
2. The presence of pressure ulcers will be evaluated by the assessor. He or she will inspect the participant's skin for pressure ulcers. Skin damage due to injuries not related to pressure (eg, cuts or burns) will not be included. Prevalence of pressure ulcers at 2 years, rather than incidence of pressure ulcers over 2 years, will be measured to avoid the need for ongoing monitoring of participants in the Control group.

This would not be feasible and could contaminate the intervention.

3. Severity of pressure ulcers will be assessed using the Pressure Ulcer Scale for Healing V.3 (PUSH). The assessor will examine the participant and rate any pressure ulcers on a scale of 0–17. The rating takes into account the area of the pressure ulcer, amount and type of exudate, and extent of tissue damage.[38] Area of the pressure ulcer will be measured using commercially available grid paper designed for this purpose. If a participant has more than one pressure ulcer, the worst pressure ulcer will be assessed. The PUSH is the most widely used tool for assessment of pressure ulcers and has demonstrated validity and sensitivity.[39 40]
4. Depression will be assessed using the Center for Epidemiologic Studies Depression Scale revised version (CESD-R). The CESD-R is a widely used instrument to screen for depression and depressive disorders. It measures symptoms defined by the American Psychiatric Association Diagnostic and Statistical Manual (DSM-IV) for a major depressive episode. The questionnaire contains 20 items, each scored on a four-point scale. Each item refers to feelings in the past week. Scores are tallied to a total score of 60, where higher scores are indicative of more depressive symptoms. The CESD-R has been translated into the Bangla language.[41 42] The questionnaire will be administered as a self-reported questionnaire under the guidance of the assessor.
5. Health-Related Quality of Life will be self-assessed using the Short Form Health Survey-12 (SF12) questionnaire. The SF12 consists of 12 questions designed to measure functional health and well-being from the individual's perspective, and is derived from the physical and mental domains of the SF36. The questionnaire has been translated into the Bangla language[43] and will be administered as a self-reported questionnaire under the guidance of the assessor.
6. Independence will be assessed using the Spinal Cord Independence Measure Self Report (SCIM-SR).[44] This is a 16-item test covering key aspects of independence. It rates self-care (4 items), respiration and sphincter management (4 items), and mobility (8 items).[45] Each item is scored and weighted differently but summed to an overall score of 100 points, where a higher score reflects more independence than a lower score. The SCIM is a valid and sensitive measure of independence for this population.[46–48] The self-report version[44] intended for telephone interview will be administered by the assessor during the face-to-face assessments.
7. Participation will be assessed using the eight participation items of the World Health Organisation Disability Assessment Schedule V.2 36 Item self-report questionnaire (WHODAS 2.0).[49] WHODAS 2.0 is a generic assessment tool for measuring health and disability. It was developed to be administered for all health conditions, across all cultures, and is valid in both, clinical and general populations. The participant is asked how much of a problem they have had with each item over the past 30 days. Each item is scored on a five-point scale ranging from none (1 point) to extreme/cannot do (5 points). The scores will be tallied to provide an overall score with a total possible score of 40, where 0 represents no problems with community participation and 40 represents extreme problems with participation. The officially translated Bangla version of the WHODAS will be administered as a self-reported questionnaire under the guidance of the assessor.
8. Out-of-bed, out-of-house and employment activities will be assessed only at the 2-year assessment. These three additional questions ask participants if they (i) got out of bed, (ii) got out of the house and (iii) engaged in paid work in the preceding week; and if so, on how many days in the preceding week this occurred. The questions have been devised specifically for this trial and translated into the Bangla language. The three questions will be self-administered under the guidance of the blinded assessor.

In addition, cost data will be collected. Participants will be asked to estimate the costs incurred over the 2 years since discharge that relate to their SCI. This may include, for example, costs of hospitalisation, visit to doctors or healthcare workers, transport for medical or rehabilitation care, catheters, wheelchairs, cushions, mattresses, vocational training, set-up for new employment, wound dressings, medications, standing or rehabilitation equipment, home modifications and vocational training. The costs of care and goods or services provided as part of the trial, including staff and training costs, will also be assessed. If participants do not know the costs of an item or service, they will be asked to provide a detailed description so an estimate of the cost can be obtained.

Sample size

The sample size of 410 gives a better than 80% probability of detecting an increase in survival from 83%[11] to 93% at 2 years with a two-sided log-rank test, uniform follow-up time of 2 years, loss to follow-up in both groups of 15% at 2 years and α of 0.05.

Data analysis

Statistical plan

All analyses will be conducted on an intention-to-treat basis, with the possible exception of secondary analyses, which will estimate complier average causal effects and survivor average causal effects. Complier average causal effects[50] on primary and secondary outcomes will be estimated if there is substantial non-compliance with the intervention, and survivor average causal effects[51] of secondary outcomes will be estimated if there is a substantially different survival in the Intervention and Control groups. The analysis will follow a detailed statistical plan developed prior to inspection of the data.

Effectiveness analysis

The primary effectiveness analysis will compare the rates of all-cause mortality in the Intervention and Control groups using the log-rank test (two-tailed α=0.05). Between-group comparisons of secondary outcomes will be conducted using linear models. In these models, the outcome will be a linear function of a dummy-coded variable representing group membership (Intervention or Control group) and a dummy-coded variable for stratum (paraplegia or tetraplegia). Baseline scores will be included in the model to increase statistical precision and statistical power.[52] If more than 5% of data are missing for a particular analysis, multiple imputation will be used to account for the missing data provided the assumption of missing at random appears plausible.[53]

Cost-effectiveness analysis

The cost-effectiveness analysis will initially involve a trial-based economic evaluation based on differences observed between groups in costs, overall survival and quality-adjusted survival at 2 years. This will enable an estimate of an incremental cost per Quality Adjusted Life Year of the intervention over standard care.

Given that the potential survival advantage will largely be that which occurs beyond 2 years, a model-based evaluation will be conducted through a state-transition model that extrapolates long-term costs and outcomes (survival and quality of life). A literature review and trial data will be used to establish the parameters in the model, including transition probabilities between health states, and costs and quality of life associated with such states. Locally relevant life tables will be used to estimate survival. These analyses will be based on the perspective of the healthcare provider. We recognise that this perspective is limited and that a broader perspective would capture costs borne by people with SCI (eg, for local healthcare services or equipment) and society. However, such costs are normally captured by diary-keeping or regular telephone follow-up. In the context of this trial, it is not feasible to ask participants to keep diaries, and regular follow-up of Control group participants would risk contamination of interventions. Instead, by taking the perspective of the healthcare provider, we will identify, measure and value costs incurred by provision of services to both, the Intervention and Control groups. Costs will be valued using standard economic evaluation guidelines. Costs will be expressed in real terms. Future costs and outcomes will be discounted at 5% per annum. The robustness of findings will be examined in sensitivity analyses.

As in all economic evaluations, the costs captured in this trial are likely to be skewed, so non-parametric bootstrap methods will be used for hypothesis tests and interval estimation. A threshold incremental cost-effectiveness ratio of three times gross domestic product per capita will be used to assess value for money.[54]

Data integrity

Data will be collected in paper format, transferred to George Clinical India, and entered into an electronic database. The data files will have identifying information removed and will be kept confidential and secure, but the data will be re-identifiable. The original Case Report Forms will be stored at the Centre for the Rehabilitation of the Paralysed. Electronically transcribed data will be stored and managed by the Biostatistics and Data Management Division of George Clinical India. Data will be double-entered with automated checks for errors. Data queries will be emailed to the site coordinator and stored on the database. George Clinical India has rigorous procedures for data protection and backup in place.

Trial management

The trial will be managed by a Steering Committee, a Management Committee and an Advisory Committee.

Site monitoring

Trial monitoring will be performed by staff from George Clinical India in coordination with the Senior Project Manager and the Clinical Research Associate. George Clinical India is affiliated with the George Institute of Global Health, Australia, and has extensive experience managing and monitoring large-scale clinical trials in Asia. Best practice conduct of the trial will be ensured through frequent monitoring by phone and in person (where possible). Site visits and site contacts will enable the independent monitors to maintain current, personal knowledge of the trial through review of the records, comparison with source documents, and observation and discussion of the conduct of the trial with the investigators and Site Coordinator. The monitors will be responsible for monitoring adherence to the protocol and with local and international guidelines,[55–57] as well as ensuring completion of the Case Report Forms and other documentation. In order to ensure the accuracy of data, the monitors, auditors, regulatory agencies, representatives of the Steering Committee, Management Committee and Ethics Committee will be given direct access to source documents, if requested. Anonymity of participants will be maintained at all times.

Trial monitoring

An independent Data Monitoring Committee (DMC) will meet periodically to monitor the safety of trial participants and the quality of trial data. The responsibilities and procedures of the DMC have been detailed in a DMC Charter.[58] The DMC will conduct an unblinded interim analysis of effectiveness and safety end points once 205 participants have completed the trial. The DMC may recommend continuing the trial, early termination of the trial, or modification of the trial. A recommendation to terminate the trial early will be made only if there is clear evidence of a clinically important beneficial or harmful effect. The trial will not be stopped early on the grounds of futility.

Provenance and ethical review

The study will be conducted in compliance with all stipulations of this protocol, the conditions of ethics committee approval, the National Health and Medical Research Council National Statement on Ethical Conduct in Human Research (2007),[59] the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95)[56] and the Bangladesh Guidance on Clinical Trial Inspection (2011).[55]

Ethic approval will be sought for all protocol modifications. Any changes to the protocol will be updated on the registry.

Serious adverse events

A serious adverse event will be defined as any event that results in death, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, or results in a persistent or significant disability or incapacity. Serious adverse events will be recorded and reported to the lead Human Research Ethics Committee.

Dissemination plan

The results of this study will be published in peer reviewed journals. It is expected that the principal investigators will co-author primary reports of the trial. Associate Investigators and trial staff may also be invited to author publications where appropriate (eg, provided they comply with the International Committee of Medical Journal Editors' policy on authorship) at the discretion of the Steering Committee. Results will also be presented at national and international conferences. To maximise the benefits to research, the re-identifiable data may be provided to approved and appropriately qualified researchers for use in future as-yet unidentified research studies.

DISCUSSION

The CIVIC trial will provide unbiased and precise estimates of the effectiveness and cost-effectiveness of an inexpensive and sustainable model of community-based care for people with SCI in Bangladesh. Evidence of effectiveness and cost-effectiveness will have widespread implications for provision of health services for people with SCI and other conditions that cause serious disability in low-income and middle-income countries.

It is anticipated that the trial will take 5 years to complete. The first participant was randomised on 12 July 2015. It is expected outcome assessments will be completed in 2019.

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Contributors MSH, LAH, RDH, IC, RL, SJB, SM and VT were responsible for the design of the intervention and the trial. MSH, LAH, RDH, IC, RL, SJ, SM, VT, FB-S, IC, RL and HSC secured funding. RDH and QL are responsible for statistical design and analysis. JB is responsible for trial support, including contributions to data acquisition and analysis and drafting the work. SJ is responsible for the economic analyses. MSH, MSI, VT, SM and AR are responsible for the local site. MD is the trial coordinator. All the authors have read and approved the final manuscript.

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Competing interests None declared.

Ethics approval Ethics Review Committees of the Centre for the Rehabilitation of the Paralysed, Bangladesh (CRP-R&E-0401-126), and the University of Sydney, Australia (2015/041).

Provenance and peer review Not commissioned; peer reviewed for ethical and funding approval prior to submission.

Data sharing statement To maximise the benefits to research, the re-identifiable data may be provided to approved and appropriately qualified researchers for use in future as-yet unidentified research studies.

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Appendix C: Case report form for the CIVIC trial

The CIVIC TRIAL

Community-based intervention to prevent serious complications following spinal cord injury in Bangladesh

Case report forms (CRF)

Assessments – English version

Principal Investigators:
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†Professor Robert Herbert, Neuroscience Research Australia, Australia

Site Principal Investigator:
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†Professor Ian Cameron, University of Sydney, Australia
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*Dr Harvinder Singh Chhabra, Indian Spinal Injuries Centre, India
*Professor Richard Lindley, George Institute for Global Health, Australia
*Professor Fin Biering-Sorensen[1], Clinic for Spinal Cord Injuries, Denmark
Mr Qiang Li, George Institute for Global Health, Australia
Dr Mushiara Mustafa Monia, Centre for the Rehabilitation of the Paralysed, Bangladesh

Funding Agency: National Health Medical Research, Australia
Participating Centres: Centre for the Rehabilitation of the Paralysed, Bangladesh
† Chief Investigators for NHMRC grant
*Associate Investigators for NHMRC grant

Contents

Participant ID: Patient initials:

Assessor name: DATE:

PARTICIPANT CONTACT DETAILS

CRP hospital ID number:	
Participant Name:	
Address after discharge:	
Phone number 1:	
Phone number 2:	
Phone number 3:	

Name of next of kin:	
Phone number 1:	
Phone number 2:	
Phone number 3:	

Name of neighbour:	
Phone number 1:	
Phone number 2:	
Phone number 3:	

Name of community leader:	
Phone number 1:	
Phone number 2:	
Phone number 3:	

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CONFIRMATION OF ELIGIBILITY

Inclusion Criteria

Please tick	Yes	No
Is the participant currently an inpatient at the Centre for Rehabilitation of the Paralysed?	☐	☐
Has the participant sustained a traumatic or non-traumatic Spinal Cord Injury within the last 2 years?	☐	☐
Is the participant aged 15 years or over at the time of consent?	☐	☐
Does the participant require a wheelchair for mobility on a daily basis?	☐	☐
About to be discharged home?	☐	☐

Exclusion Criteria

Please tick	Yes	No
Will the participant stay in Bangladesh following discharge from the Centre for Rehabilitation of the Paralysed? (i.e they are not moving to another country)	☐	☐

Are ALL the answers to the above questions YES? If so, please proceed to the Consent Phase.

If the answer to ANY of the above questions is NO, then the participant is NOT eligible to participate in the study. Add details to the screening log, but DO NOT proceed with screening.

CONSENT for all PARTICIPANTS

Purpose:

1. Ensure all participants provide a Bangla version of the informed consent form.

Instructions:

1. Participants must have the trial explained to them by an independent person and in a way that they understand.
2. Participants must have the information sheet read to them in Bangla if they are illiterate.
3. Participants must be given the Bangla version of the participant information sheet to keep.
4. Participants must be given the opportunity to ask questions.
5. Participants must be given the opportunity to discuss their involvement in the trial with their family.
6. Participants must not be coerced to participate.
7. Participants must sign a Bangla version of the consent form which must be witnessed and signed by a family member, carer or person not involved in the trial.

SUBJECT INFORMATION AND CONSENT FORM IS PROVIDED IN A SEPARATE DOCUMENT

DEMOGRAPHICS

Purpose:

1. Information required to describe the participants.

Who completes this?

1. To be completed by the assessor while interviewing the participant (the assessor will be blinded because the participant will not yet be randomised).

Version:

1. Use English version.

Instructions for assessor:

1. Ask the participant any questions you deem relevant so that together you can complete these forms.
2. Try to complete everything but if a question is irrelevant then please write NA (not applicable) but briefly explain why the question is not relevant.
3. Enter all dates as day/month/year if known. Please indicate if the day or month is not known (use NA).

Participant non-identifiable details

Date of birth: *If date of birth is not known record age in years:*	
Date of birth:	☐ Known and accurate ☐ Not known but correct within 3 years ☐ Not known and may be wrong by more than 3 years
Gender: *(please tick one only)*	☐ Male ☐ Female
Date of injury:	
Type of injury:	☐ Traumatic ☐ Non-traumatic
Date of admission to CRP:	
Expected date of discharge from CRP:	

Marital Status: *(please tick one only)*	☐ Married ☐ Not married ☐ Separated / Divorced ☐ Widowed
Is Bangla the main language spoken by the participant? *(please tick one only)*	☐ YES ☐ NO
If 'NO' please state the main language spoken by the participant.	

Participant education, social and work details

What is your ability to read and write: *(please tick the most appropriate box)*	Tick
Good ability to read and write	☐
Limited ability to read and/or write	☐
No ability to read or write	☐

BEFORE YOUR INJURY:

Before your injury, where did you live? Please describe your accommodation: (please tick one only)	☐ Own house / parent's or family member's home ☐ Renting house ☐ Own flat /parent's or family member's flat ☐ Renting flat ☐ Slum ☐ Other: (please specify)_____ _____
Before your injury, were you: *(please tick one only)*	☐ Independent at home ☐ Dependent at home ☐ Other: *(please specify)*_____
Before your injury, did you work? **If yes, what was your position/job?**	☐ YES ☐ NO _____
Before your injury, what was your work status? (please tick one only)	☐ Full time employed (i.e., worked >30 hours per week) ☐ Part time employed (i.e., worked <30 hours per week) ☐ Retired ☐ Unemployed ☐ Home duties ☐ Student ☐ Volunteer ☐ None of the above (please specify)_____
Before your injury, what was your income per month (in Taka)?	BDT _____
Before your injury, were you the main income earner in your family?	☐ YES ☐ NO

BEFORE YOUR INJURY con't:

Before your injury, how many people lived in your house with you?	Number of adults: Number of children:
Before your injury, how many other people in your household were in paid employment?	
Before your injury, what was the combined income for your house per month (in Taka)? (This amount should include the participant's income).	BDT _____

Who will be your main carer/s when you are discharged from hospital: *(please tick as appropriate)*	Tick
Independent, does not require a carer	☐
Wife or husband	☐
Mother or father	☐
Grandparent	☐
Daughter or daughter-in-law	☐
Son or son-in-law	☐
Sister	☐
Brother	☐
Paid person	☐
Other *(please specify)*	☐
Unknown	☐

Participant neurological status

Complete a full neurological assessment according to the International Standards for Neurological Classification of Spinal Cord injury on the next page.

Participant ID: Patient initials: Assessor name: DATE:

5a

RIGHT

MOTOR KEY MUSCLES

SENSORY KEY SENSORY POINTS — Light Touch (LTR) | Pin Prick (PPR)

UER (Upper Extremity Right)

Elbow flexors	C5	
Wrist extensors	C6	
Elbow extensors	C7	
Finger flexors	C8	
Finger abductors (little finger)	T1	

Comments (Non-key Muscle? Reason for NT? Pain?):

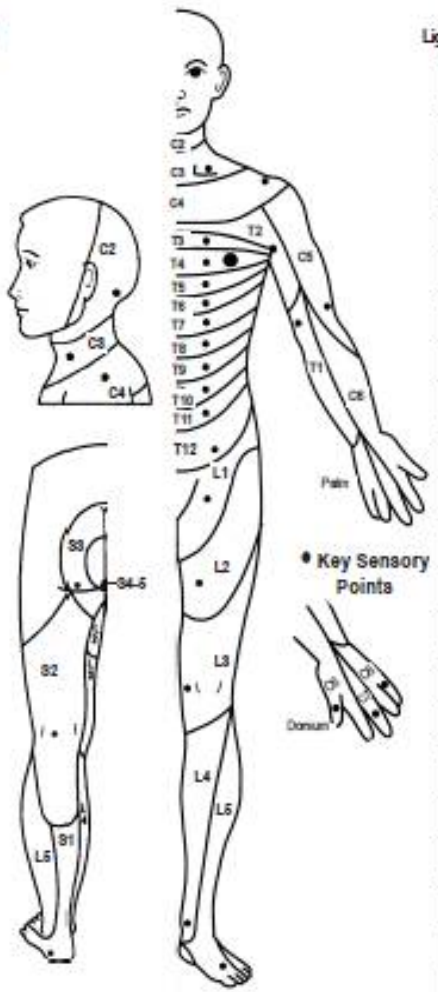
LER (Lower Extremity Right)

Hip flexors	L2	
Knee extensors	L3	
Ankle dorsiflexors	L4	
Long toe extensors	L5	
Ankle plantar flexors	S1	

C2 C3 C4 T2 T3 T4 T5 T6 T7 T8 T9 T10 T11 T12 L1 S2 S3 S4-5

(VAC) Voluntary anal contraction (Yes/No)

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



SENSORY KEY SENSORY POINTS — Light Touch (LTL) | Pin Prick (PPL)

MOTOR KEY MUSCLES

LEFT

UEL (Upper Extremity Left)

C5	Elbow flexors	
C6	Wrist extensors	
C7	Elbow extensors	
C8	Finger flexors	
T1	Finger abductors (little finger)	

LEL (Lower Extremity Left)

L2	Hip flexors	
L3	Knee extensors	
L4	Ankle dorsiflexors	
L5	Long toe extensors	
S1	Ankle plantar flexors	

C2 C3 C4 T2 T3 T4 T5 T6 T7 T8 T9 T10 T11 T12 L1 S2 S3 S4-5

MOTOR (SCORING ON REVERSE SIDE)

0 = total paralysis
1 = palpable or visible contraction
2 = active movement, gravity eliminated
3 = active movement, against gravity
4 = active movement, against some resistance
5 = active movement, against full resistance
5* = normal corrected for pain/disuse
NT = not testable

SENSORY (SCORING ON REVERSE SIDE)

0 = absent 2 = normal
1= altered NT = not testable

(DAP) Deep anal pressure (Yes/No)

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

MOTOR SUBSCORES

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

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

SENSORY SUBSCORES

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

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

NEUROLOGICAL LEVELS
Steps 1-5 for classification as on reverse

	R	L
1. SENSORY		
2. MOTOR		

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

	R	L
SENSORY		
MOTOR		

BASELINE ASSESSMENT

Purpose:

1. To understand the health of the participant at discharge. These results will be compared with the results from the 2-year assessment.

Instructions:

1. To be completed PRIOR to randomisation.
2. Try to complete in one session but if not possible then over 2 or 3 days is acceptable.
3. Ensure every item of every assessment is scored.
4. Do not give more than one response to any item in any assessment.

(NB – only secondary outcomes are measured at baseline because the primary outcome is mortality and hence not relevant at baseline).

Complications: SCI Secondary Conditions Scale

Who completes this?

1. To be completed by the assessor while interviewing the participant (the assessor will be blinded because the participant will not yet be randomised).

Version:

1. Use English version.

Instructions for assessor:

1. Ask the participant any questions you deem relevant so that together you decide on an appropriate score.
2. Rate how much you (the assessor) believe each of the listed 16 secondary conditions affect the participant's activities and independence in the last 3 months.
3. Some of these secondary conditions are expected consequences of spinal cord injury (e.g. bladder dysfunction). Rate the unexpected consequences, not the expected (e.g. do not rate as "SEVERE or CHRONIC" if a person cannot void spontaneously because this is expected. Do rate as "SEVERE or CHRONIC" if the person does not have an adequate method of managing his/her bladder and is constantly wet).
4. If the participant has not experienced the secondary condition in the last 3 months, or if it is not a significant problem for him/her, please circle ''0.'
5. Every item must be scored.

Baseline assessment

Participant ID: Patient initials:

Assessor name: DATE:

6a

SCI Secondary Conditions Scale

Code:

0 NOT experienced in the last 3 months or not a significant problem
1 MILD or INFREQUENT problem
2 MODERATE or OCCASIONAL problem
3 SEVERE or CHRONIC problem

(put a tick in one box per item only)

	0 Not experienced	**1 Mild/ infrequent**	**2 Moderate/ occasional**	**3 Severe/ chronic**
Pressure ulcer(s). This includes early signs of pressure ulcers or late stage pressure ulcers.	☐	☐	☐	☐
Injury caused by loss of sensation. This includes burns from carrying hot liquids on the lap or sitting too close to a heater or fire.	☐	☐	☐	☐
Muscle spasms (spasticity). This includes jerky involuntary movements in paralysed or partially paralysed muscles.	☐	☐	☐	☐
Contractures. This includes loss of joint mobility that is present even when a joint is slowly stretched.	☐	☐	☐	☐
Heterotopic bone ossification. This includes excessive laying down of bone. It is characterised by loss of joint mobility, local swelling and warmth at the area to the touch. This condition is diagnosed by a physician.	☐	☐	☐	☐
Diabetes mellitus. Diabetes is a problem resulting from irregularities in blood sugar levels. Symptoms include frequent urination and excessive thirst. This condition is diagnosed by a physician.	☐	☐	☐	☐
Bladder dysfunction. This includes problems related to incontinence, bladder or kidney stones, kidney problems, urine leakage and urine back up. NOTE: There is a separate item for urinary tract infections.	☐	☐	☐	☐
Urinary tract infections: This includes infections such as cystitis and pseudomonas. Symptoms include pain when urinating, a burning sensation throughout the body, blood in the urine and cloudy urine.	☐	☐	☐	☐
Bowel dysfunction: This includes diarrhoea, constipation, incontinence and associated problems.	☐	☐	☐	☐

	0 Not experienced	1 Mild/ infrequent	2 Moderate/ occasional	3 Severe/ chronic
Sexual dysfunction: This includes any difficulties that occur during any stage of normal sexual activity, including physical performance or dissatisfaction with sexual functioning.	☐	☐	☐	☐
Autonomic dysreflexia: Symptoms of dysreflexia include sudden rises in blood pressure and sweating, skin blotches, goose bumps, pupil dilation and headache.	☐	☐	☐	☐
Postural hypotension: This involves a strong sensation of light headedness following a change in position. It is caused by a sudden drop in blood pressure.	☐	☐	☐	☐
Circulatory problems: This includes swelling of the hands or feet, or blood clots.	☐	☐	☐	☐
Respiratory problems: This includes respiratory infections or problems due to difficulties breathing, coughing or clearing secretions.	☐	☐	☐	☐
Pain not related to overuse. This includes neuropathic or visceral pain or pain from any cause except overuse.	☐	☐	☐	☐
Pain in muscles or joints related to overuse injuries. This includes pain in muscles or joints which is related to overuse (typically occurs in shoulders of people who are pushing manual wheelchairs a lot).	☐	☐	☐	☐

Pressure Ulcers: Pressure Ulcer Scale for Healing (PUSH)

Who completes this?

1. To be completed by the assessor after a physical examination.

Version:

1. Use English version.

Instructions:

1. Pick the one pressure ulcer with the highest PUSH score.
2. Observe and measure the pressure ulcer.
3. Categorise the ulcer with respect to surface area, exudate (drainage), and type of wound tissue.
4. Circle a score for length, exudates (drainage) and tissue type.

Pressure Ulcer Scale for Healing (PUSH)

	Yes	**No**
Does the participant have a pressure ulcer (includes a change in skin colouring that comes prior to skin breakdown)?	☐ Continue with this assessment	☐ Progress to next assessment
Location of ulcer		

Size: Length x Width (in cm^2)	0 ☐	< 0.3 ☐	0.3 – 0.6 ☐	0.7 – 1.0 ☐	1.1 – 2.0 ☐	2.1 – 3.0 ☐
	3.1 – 4.0 ☐	4.1 – 8.0 ☐	8.1 – 12.0 ☐	12.1 – 24.0 ☐	> 24.0 ☐	

Instructions: Measure the greatest length (head to toe) and the greatest width (side to side) using the supplied grid paper. Multiply these two measurements (length x width) to obtain an estimate of surface area in square centimetres (cm^2). Do not guess! Always use a centimetre ruler and always use the same method each time the ulcer is measured.

Exudate Amount	None ☐	Light ☐	Moderate ☐	Heavy ☐

Instructions: Estimate the amount of exudate (drainage) present after removal of the dressing and before applying any topical agent to the ulcer. Estimate the exudate (drainage) as none, light, moderate or heavy.

Tissue Type	Closed ☐	Epithelial Tissue ☐	Granulation Tissue ☐	Slough ☐	Necrotic Tissue ☐

Instructions: This refers to the types of tissue that are present in the wound (ulcer) bed.

Necrotic Tissue (Eschar): black, brown, or tan tissue that adheres firmly to the wound bed or ulcer edges and may be either firmer or softer than surrounding skin.

Slough: yellow or white tissue that adheres to the ulcer bed in strings or thick clumps, or is mucinous.

Granulation Tissue: pink or beefy red tissue with a shiny, moist, granular appearance.

Epithelial Tissue: for superficial ulcers, new pink or shiny tissue (skin) that grows in from the edges or as islands on the ulcer surface.

Closed/Resurfaced: the wound is completely covered with epithelium (new skin).

Depression: Center for Epidemiologic Studies Depression Scale (CESD-R), NIMH

Who completes this?

1. To be completed solely by the participant.

Version:

1. Use Bangla version.

Instructions for assessor:

1. Give the form and a pen to the participant and ask him/her to complete.
2. If necessary, read the form and use the pen for the participant but do NOT interview or interpret the questions for the participant.
3. If a participant does not understand a question, then rephrase the question and encourage the participant to answer the question to the best of his/her ability.
4. Do not allow the participant to leave any question unanswered.

Center for Epidemiologic Studies Depression Scale (CESD-R), NIMH

Below is a list of the ways you might have felt or behaved. Please tell me how often you have felt this way during the past week.

	During the past week			
	Rarely or none of the time (less than 1 day)	Some or a little of the time (1-2 days)	Occasionally or a moderate amount of time (3-4 days)	Most or all of the time (5-7 days)
1. I was bothered by things that usually don't bother me.	☐	☐	☐	☐
2. I did not feel like eating; my appetite was poor.	☐	☐	☐	☐
3. I felt that I could not shake off the blues even with help from my family or friends.	☐	☐	☐	☐
4. I felt I was just as good as other people.	☐	☐	☐	☐
5. I had trouble keeping my mind on what I was doing.	☐	☐	☐	☐
6. I felt depressed.	☐	☐	☐	☐
7. I felt that everything I did was an effort.	☐	☐	☐	☐
8. I felt hopeful about the future.	☐	☐	☐	☐
9. I thought my life had been a failure.	☐	☐	☐	☐
10. I felt fearful.	☐	☐	☐	☐
11. My sleep was restless.	☐	☐	☐	☐
12. I was happy.	☐	☐	☐	☐
13. I talked less than usual.	☐	☐	☐	☐
14. I felt lonely.	☐	☐	☐	☐
15. People were unfriendly.	☐	☐	☐	☐
16. I enjoyed life.	☐	☐	☐	☐
17. I had crying spells.	☐	☐	☐	☐
18. I felt sad.	☐	☐	☐	☐
19. I felt that people dislike me.	☐	☐	☐	☐
20. I could not get "going.	☐	☐	☐	☐

Quality of life: SF12 - Health Related Quality of Life

Who completes this?

1. To be completed solely by the participant.

Version:

1. Use Bangla version.

Instructions for assessor:

1. Give the form and a pen to the participant and ask him/her to complete.
2. If necessary, read the form and use the pen for the participant but do NOT interview or interpret the questions for the participant.
3. If a participant does not understand a question, then rephrase the question and encourage the participant to answer the question to the best of his/her ability.
4. Do not allow the participant to leave any question unanswered.

SF12 - Health Related Quality of Life

Please answer every question. Some questions may look like others, but each one is different. Please take the time to read and answer each question carefully by filling in the bubble that best represents your response.

1. In general, would you say your health is:

- ☐ Excellent
- ☐ Very good
- ☐ Good
- ☐ Fair
- ☐ Poor

The following two questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

2. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf?
   - ☐ Yes, limited a lot
   - ☐ Yes, limited a little
   - ☐ No, not limited at all

3. Climbing several flights of stairs.
   - ☐ Yes, limited a lot
   - ☐ Yes, limited a little
   - ☐ No, not limited at all

During the past 4 weeks, have you had any of the following problems with your work or other regular activities as a result of your physical health?

4. Accomplished less than you would like?
   - ☐ Yes ☐ No

5. Were limited in the kind of work or other activities?
   - ☐ Yes ☐ No

During the past 4 weeks, have you had any of the following problems with your work or other regular activities as a result of any emotional problems (such as feeling depressed or anxious)?

6. Accomplished less than you would like?
   - ☐ Yes ☐ No

7. Didn't do work or other activities as carefully as usual?
   - ☐ Yes ☐ No

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

- ☐ Not at all
- ☐ Slightly
- ☐ Moderately
- ☐ Quite a bit
- ☐ Extremely

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks….

9. have you felt calm and peaceful?

- ☐ All of the time
- ☐ Most of the time
- ☐ A good bit of the time
- ☐ Some of the time
- ☐ A little of the time
- ☐ None of the time

10. did you have a lot of energy?

- ☐ All of the time
- ☐ Most of the time
- ☐ A good bit of the time
- ☐ Some of the time
- ☐ A little of the time
- ☐ None of the time

11. have you felt downhearted and blue?

- ☐ All of the time
- ☐ Most of the time
- ☐ A good bit of the time
- ☐ Some of the time
- ☐ A little of the time
- ☐ None of the time

12. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

- ☐ All of the time
- ☐ Most of the time
- ☐ A good bit of the time
- ☐ Some of the time
- ☐ A little of the time
- ☐ None of the time

Independence: Spinal Cord Independence Measure for Self Report (SCIM-SR)

Who completes this?

1. To be completed by the assessor while interviewing the participant and/or observing the participant.

Version:

1. Use English version.

Instructions:

1. For each item please tick the box next to the statement that best reflects your current situation.
2. Please read the text carefully and check only one (1) box in each section.
3. Every item must be scored.

Independence: SCIM-SR (Spinal Cord Independence Measure for Self Report)

1. Eating and Drinking

- ☐ I need artificial feeding or a stomach tube
- ☐ I need total assistance with eating/drinking
- ☐ I need partial assistance with eating/drinking or for putting on/taking off adaptive devices
- ☐ I eat/drink independently, but I need adaptive devices or assistance for cutting food, pouring drinks or opening containers.
- ☐ I eat/drink independently without assistance or adaptive devices.

2A. Washing your upper body and head

Washing your upper body and head includes soaping and drying, and using a water tap.

- ☐ I need total assistance.
- ☐ I need partial assistance.
- ☐ I am independent but need adaptive devices or in specific equipment (e.g., bars, chair).
- ☐ I am independent and do not need adaptive devices or specific equipment.

2B. Washing your lower body

Washing your lower body includes soaping and drying, and using a water tap.

- ☐ I need total assistance.
- ☐ I need partial assistance.
- ☐ I am independent with adaptive devices or in a specific equipment (e.g., bars, chair).
- ☐ I am independent and do not need adaptive devices or specific equipment.

3A. Dressing your upper body

Dressing the upper body includes putting on and taking off clothes like t-shirts, blouses, shirts, bras, shawls or orthosis(es) (e.g., arm splint, neck brace, corset).

- **Easy-to-dress** clothes are those **without** buttons, zippers or laces.
- **Difficult-to-dress** clothes are those **with** buttons, zippers or laces.
- **Specific settings –** including wheelchair or bed if not usually used by able-bodied people

- ☐ I need total assistance.
- ☐ I need partial assistance, even with easy-to-dress clothes.
- ☐ I do not need assistance with easy-to-dress clothes, but I need adaptive devices or specific equipment (e.g. sit on bed or in wheelchair to dress).
- ☐ I am independent with easy-to-dress clothes and only need assistance or adaptive devices or a specific setting with difficult-to-dress clothes (e.g . sit on bed or in wheelchair to dress).
- ☐ I am completely independent.

3B. Dressing your <u>lower body</u>

Dressing the lower body includes putting on and taking off clothes like shorts, trousers, shoes, socks, belts or orthosis(es) (e.g., leg splint).

- Easy-to-dress clothes are those without buttons, zippers or laces.
- Difficult-to-dress clothes are those with buttons, zippers or laces.

☐ I need total assistance

☐ I need partial assistance even with easy-to-dress clothes.

☐ I do not need assistance with easy-to-dress clothes, but I need adaptive devices or specific equipment (e.g . sit on bed or in wheelchair to dress).

☐ I am independent with easy-to-dress clothes and only need assistance or adaptive devices or a specific setting with difficult-to-dress clothes.

☐ I am completely independent.

4. Grooming

Please think about activities such as washing hands and face, brushing teeth, combing hair, shaving, applying makeup.

☐ I need total assistance.

☐ I need partial assistance.

☐ I am independent with adaptive devices.

☐ I am independently without adaptive devices.

5. Breathing

☐ I need a respiratory (tracheal) tube as well as permanent or from time to time assisted ventilation.

☐ I need a respiratory (tracheal) tube as well as extra oxygen and a lot of assistance in coughing or respiratory tube management.

☐ I need a respiratory (tracheal) tube as well as little assistance in coughing or respiratory tube management.

☐ I do not need a respiratory (tracheal) tube but I need extra oxygen or a lot of assistance in coughing or a mask (e.g., PEEP) or assisted ventilation from time to time (e.g., BIPAP).

☐ I do not need a respiratory (tracheal) tube and only a little assistance or stimulation for coughing.

☐ I do not need a respiratory (tracheal) tube and can breathe and cough independently without any assistance or adaptive devices.

6. Bladder Management

Please think about the way you empty your bladder.

6A. Use of an indwelling catheter

☐ Yes – *Please go to question 7A.*

☐ No - *Please also answer questions 6B and 6C*

6B. Intermittent catheterisation

- ☐ I need total assistance.
- ☐ I do it myself with assistance (self-catheterisation).
- ☐ I do it myself without assistance (self-catheterisation).
- ☐ I do not use it.

6C. Use of external drainage instruments (e.g., condom catheter, diapers, sanitary napkins)

- ☐ I need total assistance for using them.
- ☐ I need partial assistance for using them.
- ☐ I use them myself without assistance.
- ☐ I am continent with urine and do not use external drainage instruments.

7. Bowel Management

7.A Do you need assistance with bowel management (e.g., for applying suppositories)?

- ☐ Yes
- ☐ No

7B. My bowel movements are…

- ☐ irregular or seldom (less than once in 3 days).
- ☐ Regular (once in 3 days or more).

7C. Faecal incontinence ('accidents') happen…

- ☐ twice a month or more.
- ☐ once a month.
- ☐ not at all.

8. Using the toilet

Please think about the use of the toilet, cleaning your genital area and hands, putting on and taking off clothes, and the use of sanitary napkins or diapers.

- ☐ I need total assistance.
- ☐ I need partial assistance and cannot clean myself.
- ☐ I need partial assistance but can clean myself.
- ☐ I do not need assistance but I need adaptive devices (e.g., bars) or a special setting (e.g., wheelchair accessible toilet).
- ☐ I do not need any assistance, adaptive devices or a special setting.

9. How many of the following four activities can you perform without assistance or electrical aids?

- *Turning your upper body in bed*
- *Turning you lower body in bed*
- *Sitting up in bed*
- *Doing push-ups in wheelchair (with or without adaptive devices)*

☐ None, I need assistance in all these activities

☐ One

☐ Two or three

☐ All of them

10. Transfers from <u>bed to the wheelchair</u>

☐ I need total assistance

☐ I need partial assistance supervision or adaptive devices (e.g. sliding board).

☐ I do not need any assistance or adaptive devices.

☐ I do not use a wheelchair.

11. Transfers from the <u>wheelchair to the toilet/tub</u>

Transferring also includes transfers from the wheelchair or bed to a toilet wheelchair.

☐ I need total assistance.

☐ I need partial assistance, supervision or adaptive devices (e.g. grab-bars).

☐ I do not need any assistance or adaptive devices.

☐ I do not need a wheelchair.

12. Moving around <u>indoors</u>

☐ I use a wheelchair. To move around I need total assistance

☐ I use a wheelchair. To move around I need an electric wheelchair or partial assistance to operate manual wheelchair.

☐ I use a wheelchair. To move around I am independent in manual wheelchair.

☐ I walk indoors and I need supervision while walking (with or without devices)

☐ I walk indoors and I walk with a walking frame or crutches swinging forward with both feet at a time.

☐ I walk indoors and I walk with crutches or two canes, setting one foot before the other.

☐ I walk indoors and I walk with one cane.

☐ I walk indoors and I walk with a leg orthosis(es) only (e.g., leg splint).

☐ I walk indoors and I walk without walking aids.

13. Moving around moderate distances (10-100 metres)

I use a wheelchair. To move around,…

- ☐ I use a wheelchair. To move around I need total assistance.
- ☐ I use a wheelchair. To move around I need an electric wheelchair or partial assistance to operate a manual wheelchair.
- ☐ I use a wheelchair. To move around I am independent in manual wheelchair.
- ☐ I walk moderate distances and I need supervision while walking (with or without walking aids).
- ☐ I walk moderate distances and I walk with a walking frame or crutches, swinging forward with both feet at a time.
- ☐ I walk moderate distances and I walk with crutches or two canes, setting one foot before the other.
- ☐ I walk moderate distances and I walk with one cane.
- ☐ I walk moderate distances and I walk with a leg orthosis(es) only (e.g., leg splint).
- ☐ I walk moderate distances and I walk without walking aids.

14. Moving around outdoors for <u>more than 100 meters</u>

- ☐ I use a wheelchair. To move around I need total assistance.
- ☐ I use a wheelchair. To move around I need an electric wheelchair or partial assistance to operate manual wheelchair.
- ☐ I use a wheelchair. To move around I am independent in a manual wheelchair.
- ☐ I walk more than 100 meters and I need supervision while walking (with or without walking aids).
- ☐ I walk more than 100 meters and I walk with a walking frame or crutches, swinging forward with both feet at a time.
- ☐ I walk more than 100 meters and I walk with crutches or two canes, setting one foot before the other.
- ☐ I walk more than 100 meters and I walk with one cane.
- ☐ I walk more than 100 meters and I walk with leg orthosis(es) only (e.g., leg splint).
- ☐ I walk more than 100 meters and I walk without walking aids.

15. Going up or down stairs

- ☐ I am unable to go up or down stairs.
- ☐ I can go up or down at least 3 steps but only with assistance or supervision.
- ☐ I can go up or down at least 3 steps but only with devices (e.g., handrail, crutch or cane).
- ☐ I can go up or down at least 3 steps without any assistance, supervision or devices.

16. Transfers from the <u>wheelchair to the car</u>

Transfers include also putting the wheelchair into and taking it out of the car.

- ☐ I need total assistance.
- ☐ I need partial assistance, supervision or adaptive devices.
- ☐ I do not need any assistance or adaptive devices.
- ☐ I do not use a wheelchair.

17. Transfers from the <u>floor to the wheelchair</u>

- ☐ I need total assistance.
- ☐ I do not need any assistance.
- ☐ I do not use a wheelchair.

Participation: WHO Disability Assessment Schedule v2 (WHODAS) – Participation Items

Who completes this?

1. To be completed solely by the participant.

Version:

1. Use Bangla version.

Instructions for assessor:

1. Give the form and a pen to the participant and ask him/her to complete.
2. If necessary, read the form and use the pen for the participant but do NOT interview or interpret the questions for the participant.
3. If a participant does not understand a question, then rephrase the question and encourage the participant to answer the question to the best of his/her ability.
4. Do not allow the participant to leave any question unanswered.

WHODAS – v2 – Participation Items

In the past 30 days:

	None	Mild	Moderate	Severe	Extreme or cannot do
1. How much of a problem did you have in joining in community activities (for example, festivities, religious or other activities) in the same way as anyone else can?	☐	☐	☐	☐	☐
2. How much of a problem did you have because of barriers or hindrances in the world around you?	☐	☐	☐	☐	☐
3. How much of a problem did you have living with dignity because of the attitudes and actions of others?	☐	☐	☐	☐	☐
4. How much time did you spend on your health condition, or its consequences?	☐	☐	☐	☐	☐
5. How much have you been emotionally affected by your health condition?	☐	☐	☐	☐	☐
6. How much has your health been a drain on the financial resources of you or your family?	☐	☐	☐	☐	☐
7. How much of a problem did your family have because of your health problems?	☐	☐	☐	☐	☐
8. How much of a problem did you have in doing things by yourself for relaxation or pleasure?	☐	☐	☐	☐	☐

CONSENT CHECKLIST – Assessor to complete

Please tick	Yes	No
Has the participant been given a Participant Information Sheet?	☐	☐
Has the participant been given the opportunity to discuss the trial with a trial investigator or staff member?	☐	☐
Has the participant been given the opportunity to discuss his/her involvement with a family member or support person?	☐	☐
Has the participant signed the consent form?	☐	☐
Has the participant been given a Bangla copy of the Participant Information Sheet and signed consent form?	☐	☐

ADDITIONAL QUESTION TO BE COMPLETED BY THE ASSESSOR

How likely do you think it is that the participant will still be alive in 2 years?

Your answer should be expressed as a probability, expressed as a percentage between 0% and 100%.
A probability of 0% means you are certain the person will die within 2 years.
A probability of 50% means you think it is equally likely the participant will be dead or alive in 2 years.
A probability of 100% means you are certain the person will still be alive in 2 years.

You can nominate any number between 0% and 100%. ☐ %

(number here)

Please send demographic information and baseline assessment (pages 1a to 19a) as soon as completed to George India.

Date of Discharge

Who completes this?

1. To be completed solely by the assessor.

Version:

1. Use English version.

Instructions for assessor:

1. Only complete once the patient has left CRP.

DATE OF DISCHARGE

_____/_____/_____

day month year

Please send date of discharge (pages 20a) as soon as completed to George India.

THE PARTICIPANT WILL NOW BE RANDOMISED

Participant ID: Patient initials:

Assessor name: DATE:

Randomisation

Who completes this?

1. To be completed by the assessor AFTER they have received the randomisation from George India.

Version:

2. Use English version.

Randomisation Details

Date randomisation received: ___/_____/_____
dd / mm / yyyy

Person who advised of the randomisation: _____

Trial allocation (please tick allocation) ☐ Intervention group ☐ Control group

2-YEAR ASSESSMENT

Purpose:

1. To understand the health of the participant at 2 years. These results will be compared with the results from the baseline assessment.

Instructions:

1. All participants must have a face-to-face assessment 2 years after randomisation.
2. All assessments must be performed by a blinded and trained assessor.
3. If an assessor is inadvertently unblinded, he/she must notify the trial coordinator before proceeding.
4. Try to complete in one session but if not possible then over 2 or 3 days is acceptable.
5. Ensure every item of every assessment is scored.
6. Do not give more than one response to any item in any assessment.

Details of 2-year assessment

Date of 2-year assessment:	___/_____/_____ dd / mm / yyyy
Name of assessor:	
Position in the study:	

Mortality

	Yes	No
Has the participant died?	☐	☐

If yes, go to page 73, complete and send to George India immediately.

If no, proceed to next page (page 40) and complete full assessment.

Participant non-identifiable details

Marital Status: *(please tick one only)*	☐ Married ☐ Not married ☐ Separated / Divorced ☐ Widowed

Participant education, social and work details

These questions refer to the participant's current situation

Where do you currently live? Please describe your accommodation: (please tick one only)	☐ Own house / parent's or family member's home ☐ Renting house ☐ Own flat /parent's or family member's flat ☐ Renting flat ☐ Slum ☐ Other: (please specify)_____ _____
Are you currently: *(please tick one only)*	☐ Independent at home ☐ Dependent at home ☐ Other: *(please specify)*_____
Since your injury, have you worked?	☐ YES ☐ NO
What is your current work status? (please tick one only) **If working, what is your current position/job?**	☐ Full time employed (worked >30 hours per week) ☐ Part time employed (worked <30 hours per week) ☐ Retired ☐ Unemployed ☐ Home duties ☐ Student ☐ Volunteer ☐ None of the above (Please specify)_____ _____ _____
What is your current income per month (in Taka)?	BDT _____
Are you currently the main income earner in your family?	☐ YES ☐ NO

How many people <u>currently</u> live in your house with you?	Number of adults: Number of children:
How many other people in your household are <u>currently</u> in paid employment?	
What is the <u>current</u> combined income for your house per month (in Taka)? (This amount should include the participant's income).	BDT _____

Who is/are your main carer/s: *(please tick as appropriate)*	Tick
Independent, does not require a carer	☐
Wife or husband	☐
Mother or father	☐
Grandparent	☐
Daughter or daughter-in-law	☐
Son or son-in-law	☐
Sister	☐
Brother	☐
Paid person	☐
Other *(please specify)*	☐
Unknown	☐

Complications: SCI Secondary Conditions Scale

Who completes this?

1. To be completed by the assessor while interviewing the participant (the assessor will be blinded because the participant will not yet be randomised).

Version:

1. Use English version.

Instructions for assessor:

1. Ask the participant any questions you deem relevant so that together you decide on an appropriate score.
2. Rate how much you (the assessor) believe each of the listed 16 secondary conditions affect the participant's activities and independence in the last 3 months.
3. Some of these secondary conditions are expected consequences of spinal cord injury (e.g. bladder dysfunction). Rate the unexpected consequences, not the expected (e.g. do not rate as "SEVERE or CHRONIC" if a person cannot void spontaneously because this is expected. Do rate as "SEVERE or CHRONIC" if the person does not have an adequate method of managing his/her bladder and is constantly wet).
4. If the participant has not experienced the secondary condition in the last 3 months, or if it is not a significant problem for him/her, please circle ''0.'
5. Every item must be scored.

SCI Secondary Conditions Scale

Code:

0 NOT experienced in the last 3 months or not a significant problem
1 MILD or INFREQUENT problem
2 MODERATE or OCCASIONAL problem
3 SEVERE or CHRONIC problem

(put a tick in one box per item only)

	0 Not experienced	**1 Mild/ infrequent**	**2 Moderate/ occasional**	**3 Severe/ chronic**
Pressure ulcer(s). This includes early signs of pressure ulcers or late stage pressure ulcers.	☐	☐	☐	☐
Injury caused by loss of sensation. This includes burns from carrying hot liquids on the lap or sitting too close to a heater or fire.	☐	☐	☐	☐
Muscle spasms (spasticity). This includes jerky involuntary movements in paralysed or partially paralysed muscles.	☐	☐	☐	☐
Contractures. This includes loss of joint mobility that is present even when a joint is slowly stretched.	☐	☐	☐	☐
Heterotopic bone ossification. This includes excessive laying down of bone. It is characterised by loss of joint mobility, local swelling and warmth at the area to the touch. This condition is diagnosed by a physician.	☐	☐	☐	☐
Diabetes mellitus. Diabetes is a problem resulting from irregularities in blood sugar levels. Symptoms include frequent urination and excessive thirst. This condition is diagnosed by a physician.	☐	☐	☐	☐
Bladder dysfunction. This includes problems related to incontinence, bladder or kidney stones, kidney problems, urine leakage and urine back up. NOTE: There is a separate item for urinary tract infections.	☐	☐	☐	☐
Urinary tract infections: This includes infections such as cystitis and pseudomonas. Symptoms include pain when urinating, a burning sensation throughout the body, blood in the urine and cloudy urine.	☐	☐	☐	☐
Bowel dysfunction: This includes diarrhoea, constipation, incontinence and associated problems.	☐	☐	☐	☐

	0 Not experienced	1 Mild/ infrequent	2 Moderate/ occasional	3 Severe/ chronic
Sexual dysfunction: This includes any difficulties that occur during any stage of normal sexual activity, including physical performance or dissatisfaction with sexual functioning.	☐	☐	☐	☐
Autonomic dysreflexia: Symptoms of dysreflexia include sudden rises in blood pressure and sweating, skin blotches, goose bumps, pupil dilation and headache.	☐	☐	☐	☐
Postural hypotension: This involves a strong sensation of light headedness following a change in position. It is caused by a sudden drop in blood pressure.	☐	☐	☐	☐
Circulatory problems: This includes swelling of the hands or feet, or blood clots.	☐	☐	☐	☐
Respiratory problems: This includes respiratory infections or problems due to difficulties breathing, coughing or clearing secretions.	☐	☐	☐	☐
Pain not related to overuse. This includes neuropathic or visceral pain or pain from any cause except overuse.	☐	☐	☐	☐
Pain in muscles or joints related to overuse injuries. This includes pain in muscles or joints which is related to overuse (typically occurs in shoulders of people who are pushing manual wheelchairs a lot).	☐	☐	☐	☐

Pressure ulcers: Pressure Ulcer Scale for Healing (PUSH)

Who completes this?

1. To be completed by the assessor after a physical examination.

Version:

1. Use English version.

Instructions:

1. Pick the one pressure ulcer with the highest PUSH score.
2. Observe and measure the pressure ulcer.
3. Categorise the ulcer with respect to surface area, exudate (drainage), and type of wound tissue.
4. Circle a score for surface area, exudate (drainage) and type of wound tissue.

Pressure Ulcer Scale for Healing (PUSH)

	Yes	No
Does the participant have a pressure ulcer (includes a change in skin colouring that comes prior to skin breakdown)?	☐ Continue with this assessment	☐ Progress to next assessment
Location of ulcer		

Size: Length x Width (in cm^2)	0 ☐	< 0.3 ☐	0.3 – 0.6 ☐	0.7 – 1.0 ☐	1.1 – 2.0 ☐	2.1 – 3.0 ☐
	3.1 – 4.0 ☐	4.1 – 8.0 ☐	8.1 – 12.0 ☐	12.1 – 24.0 ☐	> 24.0 ☐	

Instructions: Measure the greatest length (head to toe) and the greatest width (side to side) using a centimetre ruler. Multiply these two measurements (length x width) to obtain an estimate of surface area in square centimetres (cm^2). Do not guess! Always use a centimetre ruler and always use the same method each time the ulcer is measured.

Exudate Amount	None ☐	Light ☐	Moderate ☐	Heavy ☐

Instructions: Estimate the amount of exudate (drainage) present after removal of the dressing and before applying any topical agent to the ulcer. Estimate the exudate (drainage) as none, light, moderate or heavy.

Tissue Type	Closed ☐	Epithelial Tissue ☐	Granulation Tissue ☐	Slough ☐	Necrotic Tissue ☐

Instructions: This refers to the types of tissue that are present in the wound (ulcer) bed.

Necrotic Tissue (Eschar): black, brown, or tan tissue that adheres firmly to the wound bed or ulcer edges and may be either firmer or softer than surrounding skin.

Slough: yellow or white tissue that adheres to the ulcer bed in strings or thick clumps, or is mucinous.

Granulation Tissue: pink or beefy red tissue with a shiny, moist, granular appearance.

Epithelial Tissue: for superficial ulcers, new pink or shiny tissue (skin) that grows in from the edges or as islands on the ulcer surface.

Closed/Resurfaced: the wound is completely covered with epithelium (new skin).

Depression: Center for Epidemiologic Studies Depression Scale (CESD-R), NIMH

Who completes this?

1. To be completed solely by the participant.

Version:

1. Use Bangla version.

Instructions for assessor:

1. Give the form and a pen to the participant and ask him/her to complete.
2. If necessary, read the form and use the pen for the participant but do NOT interview or interpret the questions for the participant.
3. If a participant does not understand a question, then rephrase the question and encourage the participant to answer the question to the best of his/her ability.
4. Do not allow the participant to leave any question unanswered.

Center for Epidemiologic Studies Depression Scale (CESD-R), NIMH

Below is a list of the ways you might have felt or behaved. Please tell me how often you have felt this way during the past week.

	During the past week			
	Rarely or none of the time (less than 1 day)	Some or a little of the time (1-2 days)	Occasionally or a moderate amount of time (3-4 days)	Most or all of the time (5-7 days)
1. I was bothered by things that usually don't bother me.	☐	☐	☐	☐
2. I did not feel like eating; my appetite was poor.	☐	☐	☐	☐
3. I felt that I could not shake off the blues even with help from my family or friends.	☐	☐	☐	☐
4. I felt I was just as good as other people.	☐	☐	☐	☐
5. I had trouble keeping my mind on what I was doing.	☐	☐	☐	☐
6. I felt depressed.	☐	☐	☐	☐
7. I felt that everything I did was an effort.	☐	☐	☐	☐
8. I felt hopeful about the future.	☐	☐	☐	☐
9. I thought my life had been a failure.	☐	☐	☐	☐
10. I felt fearful.	☐	☐	☐	☐
11. My sleep was restless.	☐	☐	☐	☐
12. I was happy.	☐	☐	☐	☐
13. I talked less than usual.	☐	☐	☐	☐
14. I felt lonely.	☐	☐	☐	☐
15. People were unfriendly.	☐	☐	☐	☐
16. I enjoyed life.	☐	☐	☐	☐
17. I had crying spells.	☐	☐	☐	☐
18. I felt sad.	☐	☐	☐	☐
19. I felt that people dislike me.	☐	☐	☐	☐
20. I could not get "going.	☐	☐	☐	☐

Quality of life: SF12 - Health Related Quality of Life

Who completes this?

1. To be completed solely by the participant.

Version:

1. Use Bangla version.

Instructions for assessor:

1. Give the form and a pen to the participant and ask him/her to complete.
2. If necessary, read the form and use the pen for the participant but do NOT interview or interpret the questions for the participant.
3. If a participant does not understand a question, then rephrase the question and encourage the participant to answer the question to the best of his/her ability.
4. Do not allow the participant to leave any question unanswered.

SF12 - Health Related Quality of Life

Please answer every question. Some questions may look like others, but each one is different. Please take the time to read and answer each question carefully by filling in the bubble that best represents your response.

1. In general, would you say your health is:

- ☐ Excellent
- ☐ Very good
- ☐ Good
- ☐ Fair
- ☐ Poor

The following two questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

2. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf?
   - ☐ Yes, limited a lot
   - ☐ Yes, limited a little
   - ☐ No, not limited at all

3. Climbing several flights of stairs.
   - ☐ Yes, limited a lot
   - ☐ Yes, limited a little
   - ☐ No, not limited at all

During the past 4 weeks, have you had any of the following problems with your work or other regular activities as a result of your physical health?

4. Accomplished less than you would like?
   - ☐ Yes ☐ No

5. Were limited in the kind of work or other activities?
   - ☐ Yes ☐ No

During the past 4 weeks, have you had any of the following problems with your work or other regular activities as a result of any emotional problems (such as feeling depressed or anxious)?

6. Accomplished less than you would like?
   - ☐ Yes ☐ No

7. Didn't do work or other activities as carefully as usual?
   - ☐ Yes ☐ No

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

- ☐ Not at all
- ☐ Slightly
- ☐ Moderately
- ☐ Quite a bit
- ☐ Extremely

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks….

9. have you felt calm and peaceful?

- ☐ All of the time
- ☐ Most of the time
- ☐ A good bit of the time
- ☐ Some of the time
- ☐ A little of the time
- ☐ None of the time

10. did you have a lot of energy?

- ☐ All of the time
- ☐ Most of the time
- ☐ A good bit of the time
- ☐ Some of the time
- ☐ A little of the time
- ☐ None of the time

11. have you felt downhearted and blue?

- ☐ All of the time
- ☐ Most of the time
- ☐ A good bit of the time
- ☐ Some of the time
- ☐ A little of the time
- ☐ None of the time

12. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

- ☐ All of the time
- ☐ Most of the time
- ☐ A good bit of the time
- ☐ Some of the time
- ☐ A little of the time
- ☐ None of the time

Independence: Spinal Cord Independence Measure for Self report (SCIM-SR)

Who completes this?

1. To be completed by the assessor while interviewing the participant and/or observing the participant.

Version:

1. Use English version.

Instructions:

1. For each item please tick the box next to the statement that best reflects your current situation.
2. 2. Please read the text carefully and check only one (1) box in each section.
3. Every item must be scored.

Independence: SCIM-SR (Spinal Cord Independence Measure for Self Report)

1. Eating and Drinking

- ☐ I need artificial feeding or a stomach tube
- ☐ I need total assistance with eating/drinking
- ☐ I need partial assistance with eating/drinking or for putting on/taking off adaptive devices
- ☐ I eat/drink independently, but I need adaptive devices or assistance for cutting food, pouring drinks or opening containers.
- ☐ I eat/drink independently without assistance or adaptive devices.

2A. Washing your upper body and head

Washing your upper body and head includes soaping and drying, and using a water tap.

- ☐ I need total assistance.
- ☐ I need partial assistance.
- ☐ I am independent but need adaptive devices or in a specific equipment (e.g., bars, chair).
- ☐ I am independent and do not need adaptive devices or specific equipment.

2B. Washing your lower body

Washing your lower body includes soaping and drying, and using a water tap.

- ☐ I need total assistance.
- ☐ I need partial assistance.
- ☐ I am independent with adaptive devices or in a specific equipment (e.g., bars, chair).
- ☐ I am independent and do not need adaptive devices or specific equipment.

3A. Dressing your upper body

Dressing the upper body includes putting on and taking off clothes like t-shirts, blouses, shirts, bras, shawls or orthosis(es) (e.g., arm splint, neck brace, corset).

- **Easy-to-dress** clothes are those **without** buttons, zippers or laces.
- **Difficult-to-dress** clothes are those **with** buttons, zippers or laces.
- **Specific settings –** including wheelchair or bed if not usually used by able-bodied people

- ☐ I need total assistance.
- ☐ I need partial assistance, even with easy-to-dress clothes.
- ☐ I do not need assistance with easy-to-dress clothes, but I need adaptive devices or specific equipment (e.g . sit on bed or in wheelchair to dress).
- ☐ I am independent with easy-to-dress clothes and only need assistance or adaptive devices or a specific setting with difficult-to-dress clothes (e.g . sit on bed or in wheelchair to dress).
- ☐ I am completely independent.

3B. Dressing your <u>lower body</u>

Dressing the lower body includes putting on and taking off clothes like shorts, trousers, shoes, socks, belts or orthosis(es) (e.g., leg splint).

- Easy-to-dress clothes are those without buttons, zippers or laces.
- Difficult-to-dress clothes are those with buttons, zippers or laces.

☐ I need total assistance

☐ I need partial assistance even with easy-to-dress clothes.

☐ I do not need assistance with easy-to-dress clothes, but I need adaptive devices or specific equipment (e.g . sit on bed or in wheelchair to dress). .

☐ I am independent with easy-to-dress clothes and only need assistance or adaptive devices or a specific setting with difficult-to-dress clothes.

☐ I am completely independent.

4. Grooming

Please think about activities such as washing hands and face, brushing teeth, combing hair, shaving, applying makeup.

☐ I need total assistance.

☐ I need partial assistance.

☐ I am independent with adaptive devices.

☐ I am independently without adaptive devices.

5. Breathing

☐ I need a respiratory (tracheal) tube as well as permanent or from time to time assisted ventilation.

☐ I need a respiratory (tracheal) tube as well as extra oxygen and a lot of assistance in coughing or respiratory tube management.

☐ I need a respiratory (tracheal) tube as well as little assistance in coughing or respiratory tube management.

☐ I do not need a respiratory (tracheal) tube but I need extra oxygen or a lot of assistance in coughing or a mask (e.g., PEEP) or assisted ventilation from time to time (e.g., BIPAP).

☐ I do not need a respiratory (tracheal) tube and only a little assistance or stimulation for coughing.

☐ I do not need a respiratory (tracheal) tube and can breathe and cough independently without any assistance or adaptive devices.

6. Bladder Management

Please think about the way you empty your bladder.

6A. Use of an indwelling catheter

☐ Yes – *Please go to question 7A.*

☐ No - *Please also answer questions 6B and 6C*

6B. Intermittent catheterisation

- ☐ I need total assistance.
- ☐ I do it myself with assistance (self-catheterisation).
- ☐ I do it myself without assistance (self-catheterisation).
- ☐ I do not use it.

6C. Use of external drainage instruments (e.g., condom catheter, diapers, sanitary napkins)

- ☐ I need total assistance for using them.
- ☐ I need partial assistance for using them.
- ☐ I use them myself without assistance.
- ☐ I am continent with urine and do not use external drainage instruments.

7. Bowel Management

7.A Do you need assistance with bowel management (e.g., for applying suppositories)?

- ☐ Yes
- ☐ No

7B. My bowel movements are…

- ☐ irregular or seldom (less than once in 3 days).
- ☐ regular (once in 3 days or more).

7C. Faecal incontinence ('accidents') happen…

- ☐ twice a month or more.
- ☐ once a month.
- ☐ not at all.

8. Using the toilet

Please think about the use of the toilet, cleaning your genital area and hands, putting on and taking off clothes, and the use of sanitary napkins or diapers.

- ☐ I need total assistance.
- ☐ I need partial assistance and cannot clean myself.
- ☐ I need partial assistance but can clean myself.
- ☐ I do not need assistance but I need adaptive devices (e.g., bars) or a special setting (e.g., wheelchair accessible toilet).
- ☐ I do not need any assistance, adaptive devices or a special setting.

9. How many of the following four activities can you perform without assistance or electrical aids?

- *Turning your upper body in bed*
- *Turning you lower body in bed*
- *Sitting up in bed*
- *Doing push-ups in wheelchair (with or without adaptive devices)*

☐ None, I need assistance in all these activities

☐ One

☐ Two or three

☐ All of them

10. Transfers from <u>bed to the wheelchair</u>

☐ I need total assistance

☐ I need partial assistance supervision or adaptive devices (e.g. sliding board).

☐ I do not need any assistance or adaptive devices.

☐ I do not use a wheelchair.

11. Transfers from the <u>wheelchair to the toilet/tub</u>

Transferring also includes transfers from the wheelchair or bed to a toilet wheelchair.

☐ I need total assistance.

☐ I need partial assistance, supervision or adaptive devices (e.g. grab-bars).

☐ I do not need any assistance or adaptive devices.

☐ I do not need a wheelchair.

12. Moving around <u>indoors</u>

☐ I use a wheelchair. To move around I need total assistance

☐ I use a wheelchair. To move around I need an electric wheelchair or partial assistance to operate manual wheelchair.

☐ I use a wheelchair. To move around I am independent in manual wheelchair.

☐ I walk indoors and I need supervision while walking (with or without devices)

☐ I walk indoors and I walk with a walking frame or crutches swinging forward with both feet at a time.

☐ I walk indoors and I walk with crutches or two canes, setting one foot before the other.

☐ I walk indoors and I walk with one cane.

☐ I walk indoors and I walk with a leg orthosis(es) only (e.g., leg splint).

☐ I walk indoors and I walk without walking aids.

13. Moving around moderate distances (10-100 metres)

I use a wheelchair. To move around,…

- ☐ I use a wheelchair. To move around I need total assistance.
- ☐ I use a wheelchair. To move around I need an electric wheelchair or partial assistance to operate a manual wheelchair.
- ☐ I use a wheelchair. To move around I am independent in manual wheelchair.
- ☐ I walk moderate distances and I need supervision while walking (with or without walking aids).
- ☐ I walk moderate distances and I walk with a walking frame or crutches, swinging forward with both feet at a time.
- ☐ I walk moderate distances and I walk with crutches or two canes, setting one foot before the other.
- ☐ I walk moderate distances and I walk with one cane.
- ☐ I walk moderate distances and I walk with a leg orthosis(es) only (e.g., leg splint).
- ☐ I walk moderate distances and I walk without walking aids.

14. Moving around outdoors for <u>more than 100 meters</u>

- ☐ I use a wheelchair. To move around I need total assistance.
- ☐ I use a wheelchair. To move around I need an electric wheelchair or partial assistance to operate manual wheelchair.
- ☐ I use a wheelchair. To move around I am independent in a manual wheelchair.
- ☐ I walk more than 100 meters and I need supervision while walking (with or without walking aids).
- ☐ I walk more than 100 meters and I walk with a walking frame or crutches, swinging forward with both feet at a time.
- ☐ I walk more than 100 meters and I walk with crutches or two canes, setting one foot before the other.
- ☐ I walk more than 100 meters and I walk with one cane.
- ☐ I walk more than 100 meters and I walk with leg orthosis(es) only (e.g., leg splint).
- ☐ I walk more than 100 meters and I walk without walking aids.

15. Going up or down stairs

- ☐ I am unable to go up or down stairs.
- ☐ I can go up or down at least 3 steps but only with assistance or supervision.
- ☐ I can go up or down at least 3 steps but only with devices (e.g., handrail, crutch or cane).
- ☐ I can go up or down at least 3 steps without any assistance, supervision or devices.

16. Transfers from the <u>wheelchair to the car</u>

Transfers include also putting the wheelchair into and taking it out of the car.

- ☐ I need total assistance.
- ☐ I need partial assistance, supervision or adaptive devices.
- ☐ I do not need any assistance or adaptive devices.
- ☐ I do not use a wheelchair.

17. Transfers from the <u>floor to the wheelchair</u>

- ☐ I need total assistance.
- ☐ I do not need any assistance.
- ☐ I do not use a wheelchair.

Participation: WHO Disability Assessment Schedule v2 (WHODAS) – Participation Items

Who completes this?

1. To be completed solely by the participant.

Version:

1. Use Bangla version.

Instructions for assessor:

1. Give the form and a pen to the participant and ask him/her to complete.
2. If necessary, read the form and use the pen for the participant but do NOT interview or interpret the questions for the participant.
3. If a participant does not understand a question, then rephrase the question and encourage the participant to answer the question to the best of his/her ability.
4. Do not allow the participant to leave any question unanswered.

WHODAS – v2 – Participation Items

In the past 30 days:

	None	Mild	Moderate	Severe	Extreme or cannot do
1. How much of a problem did you have in joining in community activities (for example, festivities, religious or other activities) in the same way as anyone else can?	☐	☐	☐	☐	☐
2. How much of a problem did you have because of barriers or hindrances in the world around you?	☐	☐	☐	☐	☐
3. How much of a problem did you have living with dignity because of the attitudes and actions of others?	☐	☐	☐	☐	☐
4. How much time did you spend on your health condition, or its consequences?	☐	☐	☐	☐	☐
5. How much have you been emotionally affected by your health condition?	☐	☐	☐	☐	☐
6. How much has your health been a drain on the financial resources of you or your family?	☐	☐	☐	☐	☐
7. How much of a problem did your family have because of your health problems?	☐	☐	☐	☐	☐
8. How much of a problem did you have in doing things by yourself for relaxation or pleasure?	☐	☐	☐	☐	☐

Participation: Out of Bed, Out of House, and Purposeful Activities Scale

Who completes this?

1. To be completed by the assessor while interviewing the participant.

Version:

1. Use Bangla version.

Instructions:

1. Please ask the participant any questions you deem relevant so that together you decide upon an appropriate score.
2. Every item must be scored.

Out of bed, out of house, purpose activities

	Yes	No
1. Have you got out of bed in the last week?	☐	☐
2. If yes, on how many days did you get out of bed in the last week (do not count days that you only got out of bed to toilet or shower)?	(*answer*: whole number between 0-7 days)	

	Yes	No
3. Have you been out of the bounds of your home property in the last week?	☐	☐
4. If yes, how many days have you been out of the bounds of your home property in the last week?	(*answer*: whole number between 0-7 days)	

	Yes	No
5. Have you worked in paid employment in the last week?	☐	☐
6. If yes, how many days have you worked in the last week?	(*answer*: whole number between 0-7 days)	
7. If yes, how much did you earn in the last week?	BDT _____	

Costs for participant

Who completes this?

1. To be completed by the assessor while interviewing the participant.

Version:

1. Use Bangla version.

Instructions:

1. Ask the participant to estimate the costs incurred over the last 2 years since discharge from CRP of everything related to his/her spinal cord injury.
2. This needs to capture costs related to – hospitalisation, visit to doctors or healthcare workers, transport for medical or rehabilitation care, catheters, wheelchairs, cushions, mattresses, vocational training, setup for new employment, wound dressings, medications, standing or rehabilitation equipment, home modifications, vocational training.
3. Include the costs of care, goods or services that may have been provided as part of this trial.
4. Ensure that the participant does not unblind the assessor while discussing costs.
5. If the participant does not know the cost then ask the participant to provide as much details as possible so we can later source a quote.
6. Add extra items if the form does on include everything.

Cost to the participant

	Yes	No
1. Have you been **hospitalised** for any reason (since discharge from CRP)?	☐	☐
If yes: How many nights in total have you spent in hospital (since discharge from CRP)?	(*answer*: whole numbers only)	

	Yes	No
2. Have you received **vocational training** at CRP (since discharge from CRP)?	☐	☐
If yes: How many nights in total have you spent at CRP receiving vocational training (since discharge from CRP)?	(*answer*: whole numbers only)	

	Yes	No
3. Have you **seen a doctor** in the community (since discharge from CRP)?	☐	☐
If yes: How many times have you seen a doctor (since discharge from CRP)?	(*answer*: whole numbers only)	

	Yes	No
4. Have you required **medications** (since discharge from CRP)?	☐	☐
If yes: How much did the medications cost you in total?	TK (*answer*: estimate total cost)	

	Yes	No
5. Have you seen a **traditional healer** (since discharge from CRP)?	☐	☐
If yes: How many times have you seen a traditional healer (since discharge from CRP)?	(*answer*: whole numbers only)	

	Yes	No
6. Have you seen any other **healthcare professional** in the community (since discharge from CRP)?	☐	☐
If yes: How many times have you seen any other healthcare professional (since discharge from CRP)?	(*answer*: whole numbers only)	

	Yes	No
7. Have you incurred costs **travelling to doctors, traditional healers, healthcare professionals or hospital** (since discharge from CRP)?	☐	☐
If yes: How much did the travel cost you in total (since discharge from CRP)?	TK (*answer*: estimate total cost)	

	Yes	No
8. Have you received a **wheelchair** (since discharge from CRP)?	☐	☐
If yes: How much did the wheelchair cost you in total (since discharge from CRP)?	TK (*answer*: estimate total cost)	

	Yes	No
9. Have you received a **cushion for the wheelchair** (since discharge from CRP)?	☐	☐
If yes: How much did the cushion for the wheelchair cost you in total (since discharge from CRP)?	TK (*answer*: estimate total cost)	

	Yes	No
10. Have you received a **mattress for your bed** (since discharge from CRP)?	☐	☐
If yes: How much did the mattress for your bed cost you in total (since discharge from CRP)?	TK (*answer*: estimate total cost)	

	Yes	No
11. Have you made any **alterations to your home** to accommodate your disability (since discharge from CRP)?	☐	☐
If yes: How much did the alterations cost you in total?	TK (*answer*: estimate total cost)	

	Yes	No
12. Have you received any other **special equipment** (since discharge from CRP)?	☐	☐
If yes: How much did the special equipment cost you in total?	TK (*answer*: estimate total cost)	

	Yes	No
13. Have you required **bladder supplies** (since discharge from CRP)?	☐	☐
If yes: How much did the bladder supplies cost you in total?	TK (*answer*: estimate total cost)	

	Yes	No
14. Have you required **bowel supplies** (since discharge from CRP)?	☐	☐
If yes: How much did the bowel supplies cost you in total?	TK (*answer*: estimate total cost)	

	Yes	No
15. Have you required **dressings or supplies for pressure ulcers** (since discharge from CRP)?	☐	☐
If yes: How much did the dressings or supplies for pressure ulcers cost you in total?	TK (*answer*: estimate total cost)	

	Yes	No
16. Have you required **money to help set up a business or get you back to work** (since discharge from CRP)?	☐	☐
If yes: How much money have you received from anyone to help set up a business or get you back to work in total?	TK (*answer*: estimate total cost)	

	Yes	No
17. Has anyone in your family **stopped working** or reduced their working so he/she can care for you (since discharge from CRP)?	☐	☐
If yes: How much income have family members lost to care for you in total (since discharge from CRP)?	TK (*answer*: estimate total cost)	

	Yes	No
18. Have you incurred any other costs related to your disability (since discharge from CRP)?	☐	☐
If yes: Itemise each item below and estimate the cost to you in total (since discharge from CRP)? Item #1: _____	TK (*answer*: estimate total cost)	
Item #2: _____	TK (answer: estimate total cost)	
Item #3: _____	TK (answer: estimate total cost)	
Item #4: _____	TK (answer: estimate total cost)	

Item #5: _____	TK (answer: estimate total cost)
Item #6: _____	TK (answer: estimate total cost)
Item #7: _____	TK (answer: estimate total cost)
Item #8: _____	TK (answer: estimate total cost)
Item #9: _____	TK (answer: estimate total cost)
Item #10: _____	TK (answer: estimate total cost)
Item #11: _____	TK (answer: estimate total cost)
Item #12: _____	TK (answer: estimate total cost)
Item #13: _____	TK (answer: estimate total cost)
Item #14: _____	TK (answer: estimate total cost)
Item #15: _____	TK (answer: estimate total cost)

BLINDED ASSESSOR QUESTIONNAIRE

Who completes this?

1. To be completed by the assessor for the assessor.

Version:

1. Use English version.

Instructions for assessor:

1. These questions refer to you as the blinded assessor.
2. Answer for yourself.

Participant ID: Patient initials:

Assessor name: DATE:

24b

Blinded Assessor - Success of blinding

	Yes	No
Have you been unblinded during this assessment?	☐	☐

(if you do not know, then guess but tick one only)

	Experimental	Control
Which group do you think the participant was in?	☐	☐

Assessor Signature:

Date:

END OF STUDY CLOSURE

Who completes this?

2. To be completed by the project coordinator.

Version:

2. Use English version.

Instructions for the project coordinator:

1. Use the checklist to indicate if the participant completed all of the study protocol, or why they did not.

.

Participant ID: Patient initials:

Assessor name: DATE:

25b

END OF STUDY CHECKLIST

(please tick one only)

	Yes	No
Did the participant complete the study as per protocol requirements?	☐	☐

If 'No' please explain: ***(please tick one only)***	**Tick**
Participant withdrew consent	☐
Participant could not be located and/or contacted	☐
Participant has died (complete form on page 73 and send to George India)	☐
Participant did not comply with the protocol *(please specify)*	☐
Other: *(Please specify)*	☐

Send *forms* 1b to 25b to George India

IN THE CASE of DEATH

Purpose:

1. To capture deaths which research staff become aware of at **ANY TIME** during the 2-year trial period.

Instructions:

1. Only complete the next page if you become aware that a control or experimental participant has died at **ANY TIME** during the 2-year trial period.
2. If a family member cannot be found to confirm that a participant has died then please find a second independent person to confirm that the participant has died.
3. Notify and send this form to your site coordinator, immediately.
4. The site coordinator will ask Shofiqul Islam or Valerie Taylor to sign the form.
5. The site coordinator will send the form to George India, immediately.
6. The site coordinator (or Shofiqul Islam) will send the form to the medical monitor/s.
   The site coordinator (or Shofiqul Islam) will notify CRP ethics.
7. George India will notify the Principal Investigators.

Participant ID: Patient initials:

Assessor name: DATE:

1c

RECORD of DEATH

(please tick one only)

	Yes	No
Has the participant died?	☐	☐

Date of death:	_____/_____/_____ day month year
Date of death:	☐ Known and accurate ☐ Not known but correct within 1 month ☐ Not known but correct within 3 months ☐ Not known but correct within 6 months ☐ Not known but correct within 1 year ☐ Not known and may be wrong by more than 1 year
Cause of death:	
Who is telling you that the participant has died? Only provide details of relationship to participant (e.g. parent of participant, friend of participant). Do not provide name on this page.	
If you are relying on someone other than a family member to tell you that the participant has died – has a second and independent person confirmed that the person has died?	☐ yes ☐ no
If yes to above – who is the second person that is telling you that the participant has died (e.g. parent of participant, friend of participant). Do not provide name on this page.	
When did you (the trial staff member) first become aware that the participant might have died? (date)	
Please record any information given regarding the death of the participant:	

Record of Death

Participant number: Participant's initials:

Trial staff's name: Date:

2G

This form needs to be signed by Shofiqul Islam or Valerie Taylor.

Name (please print): _____

Signature: _____

Date: _____ (dd/mmm/yyyy)

PLEASE send these 2 pages to George India, immediately.

Admin only: George India staff to complete:

Received by: (Signature)_____ Date:_____ Time:_____

Name and Title: _____

Record of Death

Participant number: Participant's initials:

Trial staff's name: Date:

1G

If the participant has died, please record the name and contact details of the person who confirmed the participant's death.

Name:	
Mobile phone number:	
Mobile phone number of a friend/relative of this person.	
Position in the community:	

If the above person is not a family member, then please provide the details of a second independent person who can confirm that the patient died (eg. neighbour) and provide details here.

Name:	
Mobile phone number:	
Mobile phone number of a friend/relative of this person.	
Position in the community:	

DO NOT SEND THIS PAGE TO GEORGE INDIA but put with other trial documentation for this participant

Record of Death

Participant number: Participant's initials:

Trial staff's name: Date:

1G

Date of death:	_____/_____/_____ day month year
Date of death:	☐ Known and accurate ☐ Not known but correct within 1 month ☐ Not known but correct within 3 months ☐ Not known but correct within 6 months ☐ Not known but correct within 1 year ☐ Not known and may be wrong by more than 1 year
Cause of death:	
Who is telling you that the participant has died? Only provide details of relationship to participant (e.g. parent of participant, friend of participant). Do not provide name on this page.	
If you are relying on someone other than a family member to tell you that the participant has died – has a second and independent person confirmed that the person has died?	☐ yes ☐ no
If yes to above – who is the second person that is telling you that the participant has died (e.g. parent of participant, friend of participant). Do not provide name on this page.	
When did you (the trial staff member) first become aware that the participant might have died? (date)	
Please record any information given regarding the death of the participant:	

Record of Death

Participant ID: Patient initials:

Assessor name: DATE:

2c

This form needs to be signed by Shofiqul Islam or Valerie Taylor.

Name (please print): _____

Signature: _____

Date: _____ (dd/mmm/yyyy)

PLEASE send these 2 pages to George India, immediately.

Admin only: George India staff to complete:

Received by: (Signature)_____ Date:_____ Time:_____

Name and Title: _____

Record of death

Participant ID: Patient initials:

Assessor name: DATE:

If the participant has died, please record the name and contact details of the person who confirmed the participant's death.

Name:	
Mobile phone number:	
Mobile phone number of a friend/relative of this person.	
Position in the community:	

If the above person is not a family member, then please provide the details of a second independent person who can confirm that the patient died (eg. neighbour) and provide details here.

Name:	
Mobile phone number:	
Mobile phone number of a friend/relative of this person.	
Position in the community:	

DO NOT SEND THIS PAGE TO GEORGE INDIA but put with other trial documentation for this participant

Appendix D: Interview guide for the process evaluation of the CIVIC trial

Hueiming Liu, Mohammad Sohrab Hossain, Md. Shofiqul Islam, Md. Akhlasur Rahman, Punam D Costa, Robert D Herbert, Stephen Jan, Ian D Cameron, Stephen Muldoon, Harvinder Singh Chhabra, Richard Lindley, Fin Biering-Sorensen, Stanley Ducharme , Valerie Taylor, Lisa A Harvey, on behalf of the CIVIC Trial Collaboration. **Understanding how a community-based intervention for people with spinal cord injury in Bangladesh was delivered as part of a randomised controlled trial: a process evaluation.** Spinal Cord 2020.

Supplementary file 3A: The Interview Guide for Trial Staff **(**Source 2)

THE CIVIC TRIAL-PROCESS EVALUATION
RECORD OF INTERVIEW FOR THE TRIAL STAFF

Name of Interviewer: _____

Name of others present: _____

Date: __ __ / __ __ /__ __ __ __
d d / m m / y y y y

PE ID No: _____

Role/Job title: _____

Date of birth: __ __ / __ __ /__ __ __ __
d d / m m / y y y y

Gender: Female / Male

Date commenced in current position: __ __ /__ __ __ __
m m / y y y y

Date graduated __ __ __ __
y y y y

Place of interview: CRP/ Staff members' home/ Other-please specify _____

RESEARCHER FIELD NOTES:

How do you think the interview went?

What struck you as important?

What further questions/areas would you like to explore in the next interview?

INTERVIEW GUIDE FOR THE CASE MANGERS

Key questions in bold, with probing questions in non-bold. Of note, the questions do not have to be asked in this order, and not all questions have to be covered.

Say to the staff member: Thank you for taking part in this interview. As discussed, we are trying to find out how we can better care for people with spinal cord injury (and whether the CIVIC intervention was helpful to patients).

We would like to ask you questions some questions but you are not obliged to answer them. However, if you do, please try to answer them as openly and honestly as possible. Your answers will remain confidential.

MECHANISMS OF IMPACT/CONTEXT: i.e. Exploring health care professionals' perspectives of how, why and for whom the CIVIC intervention did or did not work for?

What is your role in the CIVIC trial? Could you describe what your main responsibilities are?

- What have been some challenges?
- What have you enjoyed about your role? Could you give me an example?
- Compared to when you first started the role, and now - what have you learnt? Has this changed your care of patients with SCI?
- What could help you do your job more effectively?

What do you think were the key features of the intervention? Which were really important and why? Could you give me some examples? How was most of your time with patients spent?

- Could you tell me more about the 1st Home visit and what you would typically do? Were you surprised about anything when you visited the patient?
- What are some of the differences between the home visits and the phone calls? What did you think about the timing and frequency of the home visits and phone calls (dose)? Were they sufficient or too often?
- Did you feel that you could provide education on the prevention of pressure ulcers. If so, when you provided education on the prevention of pressure ulcers - were the patients and family carers able to follow your advice? Why or why not?
- Could you describe a typical case of how you would screen, advice and monitor for complications? What types of issues would you usually identify? What did you do then?
- Did you feel that you could support your patients emotionally and mentally? If so,

could you provide an example of how you supported a patient emotionally and mentally? (probe about relationship/intimacy support)

- Did you fell that you could advocate for greater care for your patients? If so, can you give me an example of how you advocated for greater care for a patient? When did this work or when did it not work?
- CIVIC provided financial support to patients. How were these funds commonly spent? Where there things that you would have liked to have spent money on but could not? Why is that?

Were there certain patients in your experience who would benefit more from the CIVIC intervention than others? Who and why?

- Was it different caring for patients in the rural area versus urban area?
- Was it different caring for patients in with paraplegia versus tetraplegia?
- Why do some patients have less problems post discharge compared to others?
- Why were some patients more able to comply with your advice and suggestions than others?
- Why did some patients die? In hindsight, do you think these deaths could have been prevented?

IMPLEMENTATION: i.e. Was the trial delivered as intended? Contamination? What are the barriers and facilitators to scaling up the intervention in the future?

We noted XYZ (from the chart audit, or the phone calls). What are some reasons for that?

- Was this because of the timing of the calls? New policy etc.?

What have been some barriers and facilitators in the implementation of the CIVIC intervention?

- Were there any difficulties recruiting participants?
- Was there anything we could have done to deliver the intervention better?

As you know we are hoping that the CIVIC intervention will prevent complications and mortality at 2 years. Do you think we will achieve this? Why or why not?

- Could it be due to patient level factors? e.g. unemployment and financial hardship
- Could it be due to organisational level barriers? e.g. lack of primary health providers

- Are there other policy and environmental level barriers? e.g. environment not suitable for people with to get around

If found to be beneficial, - what would be needed to get the CIVIC intervention incorporated into routine care after the trial?

- Would you want or not want to provide the CIVIC intervention in the future? Why or why not? (e.g. travel fun/tedious, too much/too little time with patients?)
- Do you think other hospitals could provide the CIVC intervention? Why or why not?
- Would the CIVIC intervention be suitable for other LMICs with a similar health system as Bangladesh?

Finally, what would be your ideal model of care post discharge for the:

- Prevention of complications
- Furthering rehabilitation outcomes
- Ensuring psychological and emotional health
- Getting patients back to work

What was your experience being involved in research? Would you be happy to be involved in another research project? Why or why not?

CONCLUDING QUESTIONS/STATEMENT

Is there anything else you would like to say that we have not talked about in this interview?

Thank you so much for your time and for sharing your insights.

Supplementary file 3B: The Interview Guide for trial participants (Source 3)

THE CIVIC TRIAL-PROCESS EVALUATION
RECORD OF INTERVIEW FOR TRIAL PARTICIPANTS

Name of Interviewer: _____

Name of others present: _____

Date: __ __ / __ __ /__ __ __ __
d d / m m / y y y y

PE ID No: _____

Participant ID number: _____

Date of birth: __ __ / __ __ /__ __ __ __
d d / m m / y y y y

Date of randomisation: __ __ / __ __ /__ __ __ __
d d / m m / y y y y

Type of Injury: Paraplegia / Tetraplegia

Gender: Female / Male

Place of interview: CRP / Participant's home / Other – please specify

_____

RESEARCHER FIELD NOTES:

How do you think the interview went?

What struck you as important?

What further questions/areas would you like to explore in the next interview?

INTERVIEW GUIDE FOR TRIAL PARTICIPANTS

Key questions in bold, with probing questions in non-bold. Of note, the questions do not have to be asked in this order, and not all questions have to be covered.

Say to the participant: Thank you for taking part in this interview. As discussed, we are trying to find out how we can better care for people with spinal cord injury (and whether the CIVIC intervention was helpful to you).

We would like to ask you questions about your injury and how you have been managing. If at any time this is distressing you, and you would like to stop, please do let us know and we can stop the interview.

CONTEXT: To understand the patient journey and health care experience

Can you tell us about your injury?

What care did you receive in the hospital?

- What were some of the good/bad things about the care you received while in hospital?

How was the rehabilitation you received while in hospital?

- What were you provided with when you were discharged? (e.g. mattress, or wheelchair, catheter?)
- Did you and your family feel like you would be able to cope after discharged home? Why or why not?

Could you describe what the first month after discharge was like for you?

- What type of supports did you get to help you?
  (Probe on family, community, religious, community health services support.)
- What did you and your carer do to prevent complications?
- Did things get better over time? How and why?

Since discharge, what supports/ services have been most important to you and why?

- Can you provide an example of a problem you had and the help you got? (e.g. pressure ulcer)
- Are you supported by other patients with SCI? (e.g. through a whatsapp chat?) Would that be helpful?
- What services were available that helped you in:
  - Preventing complications

- Rehabilitation
- Obtaining employment

How is life for you now? What is your day normally like? (e.g. are you working, relationship with family)

- Can you describe your experience in how has it been to get employment?
- How has your family coped with your injury and not working?

Is there something CRP or anyone else could have done to help you after your discharge?

Additional questions <u>only for</u> CIVIC Intervention participants:

Implementation/ mechanisms:

Satisfaction/ problems with the CIVIC intervention package for the intervention group

As you know, we are exploring if the phone calls and home visits you received were helpful. So the next questions will explore the care you received in greater detail. Please feel free to be honest about what it was like for you, as any feedback you provide will help us improve the care we provide.

What has been most helpful?

What was not helpful?

Probe further on:

- Joint goal setting for skin care and prevention of pressure ulcer
- Screening, advice and monitoring for complications
- Psychological support- level of rapport, positive and supported.
- Getting additional services
- Funding for specific things

Can you tell me about the follow up phone calls you received from CIVIC staff?

- How did you feel when a CIVIC staff member first called you?
- What did you talk about?

Can you tell me about the first home visit and how that was like for you? What about the 2nd and 3rd home visit?

- Were the home visits helpful for you? Why or why not? Can you give an example?
- Were you physically assessed and if so, how did you feel about this?
- Did staff show you how to do things and give you information? If so, was this helpful?
- Would you have liked more visits or was twice in the first year and once in the second year okay?

Specific to participants depending on their notes:

We noted in your records, that XYZ was a problem that XXX helped you with.

- Was that useful? Could you give me an example?
- What was helpful? (e.g. joint goal for skin care and prevention of pressure ulcer, advice provided, and screening of complications)
- What was not helpful? Could you describe a time when it was so.

Maintenance: Translation to current practice

Would you recommend this model of care to others? Why or why not?

As you know, this was a trial, and the cost of providing this care was covered by a research grant. Would you be willing to pay for such services in the future?

Is there anything else you would like to share with us that we have not covered?

Thank you for taking part in this study. If you have any further questions, please feel free to contact us.

Appendix E: Search strategies for the CIVIC trial

Search strategy for the CIVIC trial

Search conducted: 13th April_2020
Total article retrieved: 1738
Article after removing duplicates:1317
Article after culled: 21

Medline database search: total article found: 394

1. (Community-based or Community based or Community-based rehabilitation or Community based rehabilitation or CBR or Community-based Interventions or Community based Interventions or Community-based care or Community based care or Telephone or Tele or Home or Phone or Remote or Post-discharge or Post discharge or After discharge or Follow-up or Followup).sh,ti,ab.

2. (Communit* adj5 (rehabilitat* or health care or healthcare or health service* or health nursing* or health visitor* or health network* or care network* or counsel* or foster home* or foster care* or home care* or homecare or domiciliary care* or preventive health or health education or health promotion or self-help device* or assistive device*)).sh,ti,ab.

3. (Communit* adj5 inclusi* adj5 (education or school* or preschool* or high-school* or environment* or curricul*)).sh,ti,ab.

4. (Communit* adj5 (vocational training or apprenticeship* or employment placement service* or support network* or self-employ* or social service* or social work*)).sh,ti,ab.

5. (Communit* adj5 (personal assistance or personal assistant* or individual support* or disabled people* organization* or disabled people* organisation*)).sh,ti,ab.

6. (Communit* adj5 (empower* or awareness campaign* or self-advocacy or self-help group* or support group* or women group* or political group* or development group*)).sh,ti,ab.

7. (Communit* adj5 inclusi* adj5 (health or education or hous* or social or justice or empower*)).sh,ti,ab.

8. (rehabilitat* adj5 (home based or home-based)).sh,ti,ab.

9. (exp Rehabilitation/ or exp Rehabilitation Centers/ or ((exp Community Health Services/ or exp Social Work/ or exp Self-Help Groups/) and rehabilitat*.sh,ti,ab.)) and communit*.sh,ti,ab.

10. exp Home Care/ and rehabilitat*.sh,ti,ab.

11. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10

12. (Physical* adj5 (impair* or deficienc* or disable* or disabili* or handicap*)).sh,ti,ab.

13. (Spinal cord* or spinal inj* or paraplegi* or tetraplegi* or quadriplgi* or Paralys* or Paralyz*).sh,ti,ab.

14. ((Disable* or Disabilit* or Handicapped) adj5 (person* or people)).sh,ti,ab.

15. exp Disabled persons/

16. 12 or 13 or 14 or 15

17. (Afghanistan or Albania or Algeria or American Samoa or Angola or Antigua or Barbuda or Argentina or Armenia or Azerbaijan or Bangladesh or Belarus or Byelarus or Byelorussia or Belorussia or Belize or Benin or Bhutan or Bolivia or Bosnia or Herzegovina or Hercegovina or Bosnia-Herzegovina or Bosnia-Hercegovina or Botswana or Brazil or Brasil or Bulgaria or Burkina or Upper Volta or Burundi or Urundi or Cambodia or Republic of Kampuchea or Cameroon or Cameroons or Cape Verde or Central African Republic or Chad or Chile or China or Colombia or Comoros or Comoro Islands or Comores or Congo or DRC or Zaire or Costa Rica or Cote d'Ivoire or Ivory Coast or Cuba or Djibouti or Obock or French Somaliland or Dominica or Dominican Republic or Ecuador or Egypt or United Arab Republic or El Salvador or Eritrea or Ethiopia or Fiji or Gabon or Gabonese Republic or Gambia or Georgia or Ghana or Gold Coast or Grenada or Guatemala or Guinea or Guinea-Bisau or Guiana or Guyana or Haiti or Honduras or India or Indonesia or Iran or Iraq or Jamaica or Jordan or Kazakhstan or Kenya or Kiribati or Republic of Korea or North Korea or DPRK or Kosovo or Kyrgyzstan or Kirghizstan or Kirgizstan or Kirghizia or Kirgizia or Kyrgyz or Kirghiz or Kyrgyz Republic or Lao or Laos or Latvia or Lebanon or Lesotho or Basutoland or Liberia or Libya or Lithuania or Macedonia or Madagascar or Malagasy Republic or Malawi or Nyasaland or Malaysia or Malaya or Malay or Maldives or Mali or

Marshall Islands or Mauritania or Mauritius or Mayotte or Mexico or Micronesia or Moldova or Moldovia or Mongolia or Montenegro or Morocco or Mozambique or Myanmar or Burma or Namibia or Nepal or Nicaragua or Niger or Nigeria or Pakistan or Palau or Palestine or Panama or Papua New Guinea or Paraguay or Peru or Philippines or Romania or Rumania or Roumania or Russia or Russian Federation or USSR or Soviet Union or Union of Soviet Socialist Republics or Rwanda or Ruanda-Urundi or Samoa or Samoan Islands or Sao Tome or Principe or Senegal or Serbia or Montenegro or Yugoslavia or Seychelles or Sierra Leone or Solomon Islands or Somalia or South Africa or Sri Lanka or Ceylon or Saint Kitts or St Kitts or Saint Christopher Island or Nevis or Saint Lucia or St Lucia or Saint Vincent or St Vincent or Grenadines or Sudan or Suriname or Surinam or Swaziland or Syria or Syrian Arab Republic or Tajikistan or Tadzhikistan or Tadjikistan or Tanzania or Thailand or Timor-Leste or East Timor or Togo or Togolese Republic or Tonga or Tunisia or Turkey or Turkmenistan or Turkmenia or Tuvalu or Uganda or Ukraine or Uruguay or Uzbekistan or Vanuatu or New Hebrides or Venezuela or Vietnam or Viet Nam or West Bank or Gaza or Yemen or Zambia or Zimbabwe or Rhodesia).sh,ti,ab,cp.

18. (Africa or Asia or Caribbean or West Indies or Latin America or Central America or South America).sh,ti,ab.

19. exp Africa South of the Sahara/ or exp Asia, Central/ or exp Asia, Southeastern/ or exp Asia, Western/ or exp Latin America/ or exp Caribbean Region/ or exp Central America/ or exp South America/

20. ((Developing or Low-income or low income or Middle-income or Middle income or (Low and middle income) or (Low- and middle-income) or Less-Developed or Less Developed or Least Developed or Under Developed or underdeveloped or Third-World) adj5 (countr* or nation* or world or econom*)).sh,ti,ab.

21. (LIC or LICs or MIC or MICs or LMIC or LMICs or LAMIC or LAMICs or LAMI countr* or third world).sh,ti,ab.

22. (Transitional countr* or Transitional econom* or Transition countr* or Transition econom*).sh,ti,ab.

23. exp Developing countries/

24. 17 or 18 or 19 or 20 or 21 or 22 or 23

25. 11 and 16 and 24

26. randomized controlled trial.pt.

27. controlled clinical trial.pt.

28. randomized controlled trials/

29. random allocation/

30. double-blind method/

31. single-blind method/

32. 26 or 27 or 28 or 29 or 30 or 31

33. animals/ not (animal/ and human/)

34. 32 not 33

35. clinical trial.pt.

36. exp clinical trial/

37. (clinic$ adj25 trial$).ti,ab.

38. cross-over studies/

39. (crossover or cross-over or cross over).tw.

40. ((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).ti,ab.

41. placebos/

42. placebo$.ti,ab.

43. random$.ti,ab.

44. research design/

45. 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44

46. 45 not 33

47. 34 or 46

48. 25 and 47

49. limit 48 to yr="1976 -Current"

Embase classis+Embase database search: total article found 1046

1. (Community-based or Community based or Community-based rehabilitation or Community based rehabilitation or CBR or Community-based Interventions or Community based Interventions or Community-based care or Community based care or Telephone or Tele or Home or Phone or Remote or Post-discharge or Post discharge or After discharge or Follow-up or Followup).sh,ti,ab.

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7. (Communit* adj5 inclusi* adj5 (health or education or hous* or social or justice or empower*)).sh,ti,ab.

8. (rehabilitat* adj5 (home based or home-based)).sh,ti,ab.

9. (exp Rehabilitation/ or exp Rehabilitation Centers/ or ((exp Community Health Services/ or exp Social Work/ or exp Self-Help Groups/) and rehabilitat*.sh,ti,ab.)) and communit*.sh,ti,ab.

10. exp Home Care/ and rehabilitat*.sh,ti,ab.

11. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10

12. (Physical* adj5 (impair* or deficienc* or disable* or disabili* or handicap*)).sh,ti,ab.

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16. 12 or 13 or 14 or 15

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Serbia or Montenegro or Yugoslavia or Seychelles or Sierra Leone or Solomon Islands or Somalia or South Africa or Sri Lanka or Ceylon or Saint Kitts or St Kitts or Saint Christopher Island or Nevis or Saint Lucia or St Lucia or Saint Vincent or St Vincent or Grenadines or Sudan or Suriname or Surinam or Swaziland or Syria or Syrian Arab Republic or Tajikistan or Tadzhikistan or Tadjikistan or Tanzania or Thailand or Timor-Leste or East Timor or Togo or Togolese Republic or Tonga or Tunisia or Turkey or Turkmenistan or Turkmenia or Tuvalu or Uganda or Ukraine or Uruguay or Uzbekistan or Vanuatu or New Hebrides or Venezuela or Vietnam or Viet Nam or West Bank or Gaza or Yemen or Zambia or Zimbabwe or Rhodesia).sh,ti,ab,cp.

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21. (LIC or LICs or MIC or MICs or LMIC or LMICs or LAMIC or LAMICs or LAMI countr* or third world).sh,ti,ab.

22. (Transitional countr* or Transitional econom* or Transition countr* or Transition econom*).sh,ti,ab.

23. exp Developing countries/

24. 17 or 18 or 19 or 20 or 21 or 22 or 23

25. 11 and 16 and 24

26. (Article or Article in press or Conference abstract or Review).pt.

27. randomized controlled trials/

28. 26 and 27

29. random allocation/

30. double-blind method/

31. single-blind method/

32. 28 or 29 or 30 or 31

33. animals/ not (animal/ and human/)

34. 32 not 33

35. clinical trials/

36. exp clinical trials/

37. (clinic$ adj25 trial$).ti,ab.

38. cross-over studies/

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41. placebos/

42. placebo$.ti,ab.

43. random$.ti,ab.

44. research design/

45. 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44

46. 45 not 33

47. 34 or 46

48. 25 and 47

49. limit 48 to yr="1976 -Current"

Cochrane central register of controlled trials database search: total article found: 298

1. (Community-based or Community based or Community-based rehabilitation or Community based rehabilitation or CBR or Community-based Interventions or Community based Interventions or Community-based care or Community based care or Telephone or Tele or Home or Phone or Remote or Post-discharge or Post discharge or After discharge or Follow-up or Followup).sh,ti,ab.

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14. ((Disable* or Disabilit* or Handicapped) adj5 (person* or people)).sh,ti,ab.

15. exp Disabled persons/

16. 12 or 13 or 14 or 15

17. (Afghanistan or Albania or Algeria or American Samoa or Angola or Antigua or Barbuda or Argentina or Armenia or Azerbaijan or Bangladesh or Belarus or Byelarus or Byelorussia or Belorussia or Belize or Benin or Bhutan or Bolivia or Bosnia or Herzegovina or Hercegovina or Bosnia-Herzegovina or Bosnia-Hercegovina or Botswana or Brazil or Brasil or Bulgaria or Burkina or Upper Volta or Burundi or Urundi or Cambodia or Republic of Kampuchea or Cameroon or Cameroons or Cape Verde or Central African Republic or Chad or Chile or China or Colombia or Comoros or Comoro Islands or Comores or Congo or DRC or Zaire or Costa Rica or Cote d'Ivoire or Ivory Coast or Cuba or Djibouti or Obock or French Somaliland or Dominica or Dominican Republic or Ecuador or Egypt or United Arab Republic or El Salvador or Eritrea or Ethiopia or Fiji or Gabon or Gabonese Republic or Gambia or Georgia or Ghana or Gold Coast or Grenada or Guatemala or Guinea or Guinea-Bisau or Guiana or Guyana or Haiti or Honduras or India or Indonesia or Iran or Iraq or Jamaica or Jordan or Kazakhstan or Kenya or Kiribati or Republic of Korea or North Korea or DPRK or Kosovo or Kyrgyzstan or Kirghizstan or Kirgizstan or Kirghizia or Kirgizia or Kyrgyz or Kirghiz or Kyrgyz Republic or Lao or Laos or Latvia or Lebanon or Lesotho or Basutoland or Liberia or Libya or Lithuania or Macedonia or Madagascar or Malagasy Republic or Malawi or Nyasaland or Malaysia or Malaya or Malay or Maldives or Mali or Marshall Islands or Mauritania or Mauritius or Mayotte or Mexico or Micronesia or Moldova or Moldovia or Mongolia or Montenegro or Morocco or Mozambique or Myanmar or Burma or Namibia or Nepal or Nicaragua or Niger or Nigeria or Pakistan or Palau or Palestine or Panama or Papua New Guinea or Paraguay or Peru or Philippines or Romania or Rumania or Roumania

or Russia or Russian Federation or USSR or Soviet Union or Union of Soviet Socialist Republics or Rwanda or Ruanda-Urundi or Samoa or Samoan Islands or Sao Tome or Principe or Senegal or Serbia or Montenegro or Yugoslavia or Seychelles or Sierra Leone or Solomon Islands or Somalia or South Africa or Sri Lanka or Ceylon or Saint Kitts or St Kitts or Saint Christopher Island or Nevis or Saint Lucia or St Lucia or Saint Vincent or St Vincent or Grenadines or Sudan or Suriname or Surinam or Swaziland or Syria or Syrian Arab Republic or Tajikistan or Tadzhikistan or Tadjikistan or Tanzania or Thailand or Timor-Leste or East Timor or Togo or Togolese Republic or Tonga or Tunisia or Turkey or Turkmenistan or Turkmenia or Tuvalu or Uganda or Ukraine or Uruguay or Uzbekistan or Vanuatu or New Hebrides or Venezuela or Vietnam or Viet Nam or West Bank or Gaza or Yemen or Zambia or Zimbabwe or Rhodesia).sh,ti,ab,cp.

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20. ((Developing or Low-income or low income or Middle-income or Middle income or (Low and middle income) or (Low- and middle-income) or Less-Developed or Less Developed or Least Developed or Under Developed or underdeveloped or Third-World) adj5 (countr* or nation* or world or econom*)).sh,ti,ab.

21. (LIC or LICs or MIC or MICs or LMIC or LMICs or LAMIC or LAMICs or LAMI countr* or third world).sh,ti,ab.

22. (Transitional countr* or Transitional econom* or Transition countr* or Transition econom*).sh,ti,ab.

23. exp Developing countries/

24. 17 or 18 or 19 or 20 or 21 or 22 or 23

25. 11 and 16 and 24