The Impact of an Evidence-Informed Spinal Cord Injury Activities of Daily Living Educational Manual (SADL-eM): study protocol for a randomized clinical trial

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Abstract

Background: This study argues that providing evidence-based occupational therapy patient education is vital in order to optimize rehabilitation outcomes. The planned trial aims to evaluate the SADL-eM intervention for people with SCI compared with standard treatment.

Methods/Design: This is a parallel randomized clinical trial with two study arms, intervention and control. Ninety patients treated in inpatient rehabilitation settings will be randomly allocated to two study groups. Both groups will receive standard care. The intervention group will also receive a copy of the SADL-eM from their treating occupational therapist during an individual session. Assessment on admission (baseline measure) and after six weeks of admission will use the SCIM-SR as the primary outcome measure. Secondary outcomes include the SCIM-III, Private Religiousness Practices Scale, Organizational Religiousness Short-Form, additional domains of ADL covered by the educational manual and adherence to intervention. Effect will be determined using repeated measures ANOVA.

Discussion: The SADL-eM is a comprehensive ADL educational tool that aims to optimize rehabilitation outcomes for people with SCI. If the SADL-eM is demonstrated as clinically effective, this will have significant implications for occupational therapy interventions in LMIC settings.

Trial registration: BLINDED FOR REVIEW (Project ID: 1635, HREC Reference number: S17/10/206). Helsinki Committee for Ethical Approval (PHRC/HC/689/20)

Date of registration: 30/11/2017, Renewed 12/06/2020

Keywords: Occupational therapy, educational intervention, Activities of daily living, Spinal Cord Injury, clinical trials

Introduction

Patient education is gaining more interest especially during the time of COVID-19 (Wasson, 2020). People with SCIs requiring inpatient rehabilitation in the Gaza Strip complete their medical management in a secondary healthcare facility and arrange for subsequent referral and admission to an inpatient rehabilitation setting. Due to limited resources, many patients are added to waiting list before admission. Providing functional therapy and health education as the main objectives of inpatient rehabilitation for people with spinal cord injury in Low and Middle Income Countries (LMIC) is being limited by shorter length of stay (LOS) in inpatient rehabilitation settings and inadequate community rehabilitation. Some inpatients are being discharged home with less skills in Activities of Daily Living (ADL), mobility, and prevention of medical complications. These challenges increase the demand for evidence based educational interventions including ADL education during inpatient care, that improves rehabilitation outcomes (Mostafa, Plastow, and Savin-Baden, 2019).

SCI patient education aims to develop knowledge, skills, attitudes, and behaviors to maintain health and wellbeing, prevent secondary complications, and enhance active life participation (Mostafa, et al., 2019). Topics presented early in the admission phase may include body anatomy and functioning, while others like community integration can be presented at later phases of rehabilitation so that SCI individuals will become progressively independent in activities of daily living (Letts et al., 2011).

An effective SCI educational manual should be accessible and motivating in terms of information, details, and layout. It should provide support, for example web groups, consultations, and answers to common questions. An SCI educational manual must also be cost-effective, up-to-date and meet the needs of people from different backgrounds, preferences, genders and ethnicities (Chou, et al., 2012). It is important that SCI educational manuals targeting adults provide autonomy and are guided by adult learning theory to facilitate active roles of people with SCI (May, Day, and Warren, 2006). Staff availability (time allocated

for patient education) and patient readiness (motivation and interest) are two important concerns for effective patient education. Time allocated for patient education can be limited and inadequate due to patient treatment workload and staffing shortages. Decreased motivation and interest of the patient during rehabilitation adds another barrier to patient education (Shepherd, et al., 2012).

This study plans to evaluate the impact of providing an evidence-informed SCI ADL educational manual (SADL-eM) on activities of daily living among people undergoing rehabilitation for a spinal cord injury in the Gaza Strip, Palestine. This study may counter the effect of decreased LOS in rehabilitation in this LMIC context. By improving patient education, the authors intend to improve patients' involvement in their treatment during their stay in the three inpatient rehabilitation settings available in the Gaza Strip. An effective educational intervention will enhance the quality of care and reduce the cost of healthcare services in the long term.

This aim of the proposed study is to evaluate the impact of a SADL-eM on activities of daily living. This educational intervention is delivered to inpatients with SCI in a rehabilitation setting.

Research question

Does the implementation of a SADL-eM delivered to SCI patients in an inpatient rehabilitation setting in the Gaza Strip have a significant impact on activities of daily living?

Primary objectives

a. To describe the characteristics of the participants (people with SCI in the Gaza Strip using the Biographical Data Form developed for this study).
b. To compare the effect of the educational manual, relative to usual care, on self-reported changes in activities of daily living from admission to 6-weeks post-admission, using the SCIM-SR patient-rated measure.
c. To compare the effect of the educational manual, relative to usual care, on observed changes in activities of daily living from admission to 6-weeks post-admission, using the SCIM-III clinician-rated measure.
d. To compare the effect of the education manual, relative to usual care, on religious practice using the Private Religiousness Practices Scale and Organizational Religiousness Short-Form.

e. To compare the effect of the education manual, relative to usual care, on the domains of ADL covered by the education manual including driving and community mobility, personal device care, health management and maintenance, Wudu, and Salat, using questions developed for this research.

Secondary objectives

f. To determine the significance of biographical variables (Address zone, Age, Gender, Highest level of Education, Marital status, Employment status, Monthly income, Level of SCI, Type of SCI 'complete/incomplete'), ASIA, and Dysfunction on the progress of ADL.
g. To measure the adherence to the intervention using the SADL-eM adherence therapist-report questionnaire which will be developed for this purpose.

Research Hypothesis

a. **Null hypothesis**: There is no difference between the SADL-eM and the standard care delivered to inpatients with SCI in a rehabilitation setting.
b. Alternative hypothesis: The implementation of a SADL-eM delivered to inpatients with SCI in a rehabilitation setting has a significant impact on their ADL.

Methodology

Study Design

Please insert Figure 1 (Study Flow Diagram) here

This is a parallel, single blinded (assessor) randomized clinical trial (RCT) with a pre-/post-test to evaluate a hypothesis of cause-and-effect relationship. This study uses the Consolidated Standards of Reporting Trials (CONSORT) statement as the proposed standard for the reporting of parallel-group RCTs (Moher et al., 2010).

Participants, sampling method, sample size, and setting

Participants in the study will be SCI inpatients from the Gaza Strip, both genders, of any cause or type of SCI, and age 18-65 years. They will be recruited from admitted inpatients in one of the three rehabilitation settings (Hamad, ElWafa, or ElAmal Rehabilitation hospitals). Readmissions will be included in the study if they are eligible. These three inpatient rehabilitation hospitals are located in the Gaza Strip of Palestine and are private sector health services. They provide comprehensive rehabilitation services. Their rehabilitation teams include physical rehabilitation doctors, rehabilitation nurses, physiotherapists, occupational

therapists, speech therapists, clinical dietitians, psychologists, social workers, orthoptists, and community-based rehabilitation workers. The sample size was determined to detect an effect size of 15%, power of 80%, 5% margin of error, and 95% Confidence Interval (CI). The study sample of 90 SCI individuals will be randomized to two groups, conventional therapy (n1=45) and intervention/SADL-eM & conventional therapy (n2=45) using a simple randomization approach. Inclusion and exclusion criteria are listed in Box 1.

Please insert box 1 (inclusion and exclusion criteria) here

Pilot study

Pilot studies are small-sample, preliminary studies which aim to investigate the feasibility of a study. RCTs usually use pilot studies to improve feasibility and avoid crucial barriers (Bell, Whitehead, and Julious, 2018). A small number (15) of participants with SCI of any cause and of any type aged 18-65 years with a previous inpatient rehabilitation experience will take part in the pilot study. They will be selected from the 2019-2020 inpatient list of Hamad Rehabilitation Hospital. They will complete the Spinal Cord Independence Measure-Self Reported (SCIM-SR). A well-trained research assistant (physiotherapist) will administer the biographical data collection tool, the Spinal Cord Independence Measure-III (SCIM-III), the Private Religiousness Practices Scale, Organizational Religiousness Short-Form, and the domains of ADL covered by the educational manual including driving and community mobility, personal device care, health management and maintenance, Wudu, and Salat. The patients and the research assistant will comment on the tools employed and point out any problems with the tests' instructions, instances where items are not clear, and formatting and other typographical errors and/or issues. Each question measures performance/participation in ADL will be analyzed using the Cronbach's Alpha to test and improve reliability.

SCI ADL Educational Manual (SADL-eM)

Both study groups will receive usual care. In addition, each participant in the experimental group will receive a copy of the SADL-eM from their occupational therapist with a short discussion about its importance and use.

The SADL-eM was developed by the authors following a systematic review (BLINDED FOR REVIEW) and user-led development project. A team of 54 Subject Matter Experts (SME) collaborated in a Participatory Action Research (PAR) project to develop the manual. The researchers used eight consecutive focus groups and Nominal Groups Technique (NGT) for

consensus. The manual production took 17 months and is to our knowledge the first comprehensive SCI ADL educational tool available in Arabic.

The SADL-eM includes three elements essential to the intervention, namely: knowledge, skills, and advice. The manual includes 92 A5 pages with six detailed sections: an Introduction and five chapters: (1) Rehabilitation team, (2) Activities of Daily Living, (3) Assistive devices, (4) Home environment adaptation, and (5) Knowledge guide. The SADL-eM uses text and illustrative pictures that are carefully selected for contextual relevance. The manual is simple, easy, and suitable for people with a non-medical background. However, good Arabic language comprehension, read and write is mandatory for users. No other special skills or experience are required.

The purpose of the SADL-eM is to serve as a treatment tool during inpatient rehabilitation. Over the first week of admission of each person with SCI in each facility, a research clinical supervisor will recruit study participants based on the study eligibility criteria, obtain consent, and assign each consenting patient to one of the two study groups. They will then provide each participant in the intervention group with a SADL-eM hard copy, and explain the purpose of the manual and how to use it. The manual will be reviewed by the treating occupational therapist and the person with SCI during their treatment sessions. During occupational therapy sessions, the therapist will refer to the relevant chapter of the manual. The therapist will also indicate to the participants which parts of the manual are not relevant to them (based on their gender, driving status, or level of SCI). Participants' queries on the content of the manual will be answered by the treating occupational therapist. The therapist will include the manual in as many SADL-eM educational sessions as required, but not less than three sessions per week with 15 minutes per session. The minimum level of clinical experience of each treating occupational therapist will be two years. Good Arabic language comprehension, and the ability to read and write is mandatory for both therapists and patients. No other special skills or experience are required.

The participants will keep the manual to review after sessions and after discharge from the inpatient rehabilitation setting. For the purposes of the study, blinding and bias reduction, the therapists and the participants in the intervention group must not share any part of the manual or information included with other patients or staff. The research assistant who performs data collection, the clinical supervisor, and occupational therapy team will be invited for informational session prior to data collection in each of the participating settings. The informational session will focus on the study purpose, recruitment, eligibility criteria, use of

the SADL-eM, roles, bias reduction, and blinding. Use of data collection tools will take place in a separate session with the research assistant. The principal researcher will answer all questions of the research team during informational sessions and during the research.

For the purposes of the current study, the SADL-eM will be provided during face-to-face individual occupational therapy sessions without any constrains regarding treatment area. It could be occupational therapy department, patient ward, and educational activities room. The face-to-face manual delivery does not require any infrastructure or special equipment.

The number of sessions, time allocated, and frequency are determined by each therapist and participant. Determinants may include participant's capabilities, potentials, and progress during treatment; and the scope of the service such as time allocated for each patient, therapist-patient ratio, and frequency of inpatient sessions. The therapist and the participant will continue to use the manual during treatment sessions until they decide there is no need for further use of the manual or the participant is discharged. Treating occupational therapists will retain records of any change or modification of the SADL-eM administration. The researchers will conduct a pilot study in a similar sample of 15 S people with SaCIs to improve the use of intervention and data collection tools.

Nonadherence to medical treatment in clinical trials of medical efficacy has serious consequences on the quality of research. It may obscure data collected and disrupt findings obtained (Quittner, et al., 2000). The steps to ensure adherence to the intervention during study include clearly defining the intervention, measuring, and then comprehensively reporting adherence to the intervention. Attendance records collected by the therapist (times, duration, and intensity of treatment; manual elements covered) and SADL-eM adherence therapist-report questionnaire will be used to measure and report adherence to the SADL-eM intervention. The manual will be made freely available on the Stellenbosch University website when the research is complete.

Data Collection

All admitted SCI patients will be evaluated by the research supervisor in the setting for eligibility within three days of admission to the inpatient rehabilitation setting, until the desired sample size is reached. Eligible individuals will sign a consent form and then be assigned randomly to one arm of the study by the research supervisor. The allocation sequence will be concealed from patients, therapist and, assessor. The data about exposure to the educational intervention will be collected by a separate research assistant by phone and will be concealed

from the assessor. Each occupational therapy department will assign four therapists to follow up the trial cases – two for the intervention and two for control group. All the staff in the occupational therapy department, participants, and assessors will be requested not to discuss the trial and intervention material between them. The importance of concealing any information until the end of the study will be explained. Study participants are not allowed to switch between occupational therapists or study arms. They will be asked not to participate in other educational interventions (peer or external) related to their rehabilitation or seek treatment outside their trial. The head of occupational therapy department within each rehabilitation setting will supervise participants and assigned occupational therapists in both study arms to reduce contamination bias such as sharing intervention content with the control group, sharing similar time and space of occupational therapy sessions, and exchange of therapists.

Contamination bias due to already existing background and/or receipt of additional educational interventions will be measured within each arm of the study (Chi-Square test to compare the progress means). However, no case will be eliminated from statistical analysis due to contamination bias.

The study will adopt approaches to prevent loss of participants to follow-up by making questionnaires as easy to complete as possible, providing incentives in the form of a free copy of the educational manual for the control group, and explaining the importance of the study (Magill, et al., 2019).

The researchers will use the same outcome measures all through the study and with both of study arms. Biographical data will be collected by a research assistant once on the participant's admission and consent to participate. ADL data collection from each participant in the study will take place in a face-to-face interview twice (on admission before providing with the educational manual and 6 weeks later) using: (a) Patient-administered SCIM-SR and (b) Research assistant-administered SCIM-III, the Private Religiousness Practices Scale, Organizational Religiousness Short-Form, and the domains of ADL covered by the educational manual including driving and community mobility, personal device care, health management and maintenance, Wudu, and Salat. The data will be used to compare the results and means of both groups, answer the research question, and test the study hypothesis.

Polit, et al. (2001) pointed out that the validity of the experimental study can be threatened by history, selection, and maturation. This study finding's validity will be enhanced by concealing intervention group using a blinded assessor. The bias of sampling and contamination will be

minimized through randomization and assuring freedom of participation and anonymity of participants.

Objective data collected in clinical settings using valid and reliable tools is essential for evaluating the impact of an intervention (Polit, et al., 2001). The validity and reliability of the data collected and results of the study will be improved using standardized measurement tools such as SCIM-III and SCIM-SR.

Biographical Data Collection Tool: an English 24-item tool that captures demographic and socioeconomic data including age, gender, marital status, level of education, employment, monthly income, accommodation, diagnosis, and cause and type of SCI. The researchers developed the tool to be used in English version in this study.

Spinal Cord Independence Measure-Self Reported (SCIM-SR): a patient-reported 17-item tool that evaluates the ability of a person with SCI to perform specified activities independently, with assistance, or with assistive devices. The tool uses an ordinal scale. Research supports the criterion validity of SCIM-SR as compared with SCIM III. Pearson correlation and ICC coefficients of the total and the subscale scores met the quality criterion of being above 0.7. The tool is not available in Arabic (Fekete, et al., 2013). The first author will translate the SCIM-SR to Arabic. The Arabic translation will be piloted in the pilot study.

Spinal Cord Independence Measure-III (SCIM-III): a 17-task tool that evaluates the ability of a person with SCI to perform specified activities independently, with assistance, or with assistive devices. It is therapist-reported and requires 30 to 45 minutes to complete by assessment but, the interview requires less time [about 20 minutes] (Fekete, et al., 2013). The SCIM has been evaluated in multiple countries including the Middle East and it appears to be resistant to cross-cultural differences. The SCIM-III is valid for use in clinical practice to evaluate function and plan goals of rehabilitation (Glass, et al., 2009). The tool uses an ordinal scale with total score range between 0-100. A higher score indicates greater ADL performance. The SCIM-III has good reliability: Cronbach's alpha: 0.70-0.78, Kappa co-

efficient: 0.64-0.84. Pearson correlation and ICC coefficients of the total and the subscale scores met the quality criterion of being 0.84-0.94. The tool is not available in Arabic and will be used in its English version (Anderson, et al., 2008). Good English language comprehension, and the ability to read and write is mandatory for therapists.

The Private Religious Practices Scale: a 4-item tool that measures the frequency of individual's involvement in religious behaviours: prayer, religious attendance (attending a church or mosque), reading the Bible/Quran, and watching religious programs on television (Fetzer Institute, 2003). The tool uses an ordinal scale and it has acceptable reliability (a=0.70). It can be therapist-reported or patient-reported. The tool is not available in Arabic and will be used in its English version (Bodling, et al., 2013).

Organizational Religiousness Short-Form: a 2-item tool that measures the involvement of the individual with a formal public religious institution such as a church or mosque (Fetzer Institute, 2003). The tool uses an ordinal scale and has accepted reliability (a=0.70-0.76). It can be therapist-reported or patient-reported. The tool is not available in Arabic and will be used in its English version (Bodling, et al., 2013).

SADL-eM adherence therapist-report questionnaire: Based on the Morisky Medication Adherence Scale [MMAS] (De las Cuevas and Penate, 2015), this tool measures any change to the supplied SADL-eM in terms of content of the intervention, topics, techniques described, mode, format, and degree of individualization of the intervention. The tool keeps record of educational sessions by day, duration, intensity, and elements covered. This tool was developed by the researchers and will be used in its English version.

Monitoring

The three researchers will monitor the study on monthly bases during online meetings. Progress, barriers, and action plans will be discussed at each meeting.

Data Analysis

Captured data will be coded and reviewed by the researchers for clarity and completion. A spread sheet will be prepared by the three researchers and then loaded to IBMSPSS 21 for analysis. The first author will perform data entry. The research assistant will check the data entry using the original forms, and the research supervisor will check the data for missing data and entry errors.

The following statistical methods will be used to test the research hypothesis:

a. To describe participants' characteristics: descriptive statistics such as frequency, percentage, mean with standard deviation for Normally distributed data and median and Inter Quartile range will be used for continuous variables that are not Normally distributed will be used.
b. Missing values will not be substituted. Intention-to treat analysis method will be used for analysis.
c. To determine the significance of biographical variables at baseline: McNemar and Chi Square with Nominal variables, T-test and Mann-Whitney for interval variables will be used.
d. To compare the efficacy of the educational manual: Repeated Measures ANOVA/ Linear Mixed Models will be used will be used to assess differences between intervention and control group using the ADL data. The Repeated Measures ANOVA and Linear Mixed Models will be used to analyze the data. Linear Mixed Models has advantage in dealing with missing values and provides fixed and random effect (Krueger and Tian, 2004).
e. Adherence to the intervention will be summarized using frequency and percentage.

All the data collected and entered (hardcopy and soft copy) will be securely stored by the first researcher in a locked cabinet on hospital premises (hardcopy) and in a password-protected file online.

Ethical Issues

Ethical approval will be obtained from the BLINDED University Human Research Ethics Committee (HREC). Autonomy of participation or withdrawal, the anonymity of participants, and confidentiality of information collected for research reasons will be assured in the consent form and sustained all through study. The study is unlikely to involve any harm, risk or discomfort to participants. Patients' questions will be answered by the researcher honestly and as fully as possible. Completed questionnaires and signed consents of participants will be

securely stored during and after study completion in a locked cabinet on hospital premises for a period of 5 years after publication. The participants in the control group will receive a copy of the SADL-eM at the end of study with explanation from the researcher.

Protocol amendments

The researchers will communicate important protocol modifications such as changes to eligibility criteria, outcomes, and analyses to HREC of BLINDED University under the regulations of the Helsinki Declaration.

Access to data

Anonymized data will be available for peer review or quality appraisal. Any other data sharing will require the approval of the three researchers, as well as ethical approval from the requesting party.

Dissemination policy

The study manuscript will be submitted for publication in a relevant peer-reviewed journal, and further dissemination through conference presentations. The SADL-eM will be made freely available on the XX University website in Arabic, with a summary in English.

COVID-19 precautions

The treating occupational therapists and research assistant will follow the required COVID-19 precautions published by the WHO (DiSilvio, et al., 2020) and applied by each facility. This includes use of medical disposable gowns, disposable latex gloves, face shield, surgical mask, and hand hygiene using alcohol 70% or alcohol gel. These supplies will be provided by each facility as requirements of usual treatment.

Discussion

Providing occupational therapy patient education that aim to improve the performance of patients with SCI in their ADL can optimize the outcomes of rehabilitation. The SADL-eM is an evidence-informed manual that supports a client-centred approach and aims to teach patient with SCI how to handle their ADL after injury and during inpatient rehabilitation phase. Quality and well-controlled clinical trials are essential to develop effective interventions for people with SCI. This randomized clinical trial aims to evaluate the impact of the SADL-eM intervention with SCI patients in inpatient rehabilitation setting in the Gaza strip, Palestine. If

the SADL-eM is demonstrated to be clinically effective, it will have significant implications for occupational therapy research and practice.

Trial status

Recruitment is expected to start by March 2021 and is due to continue until the February 2022. The pilot study will start in January 2020.

Abbreviations

ADL: Activities of Daily Living, SCI: Spinal Cord Injury, SCIM-III: Spinal Cord Independence Measure-III, SCIM-SR: Spinal Cord Independence Measure-Self-Reported, SADL-eM: SCI ADL Educational Manual

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

MAM, MSB, and NAP developed the concept for the trial; drafted the protocol; contributed to the trial design and methodology; developed the SADL-eM intervention; adapted the trial protocol as a protocol paper; and reviewed and commented on drafts of the paper and approved the final version. MAM, MSB, NAP, and AB developed the statistical analysis plan.

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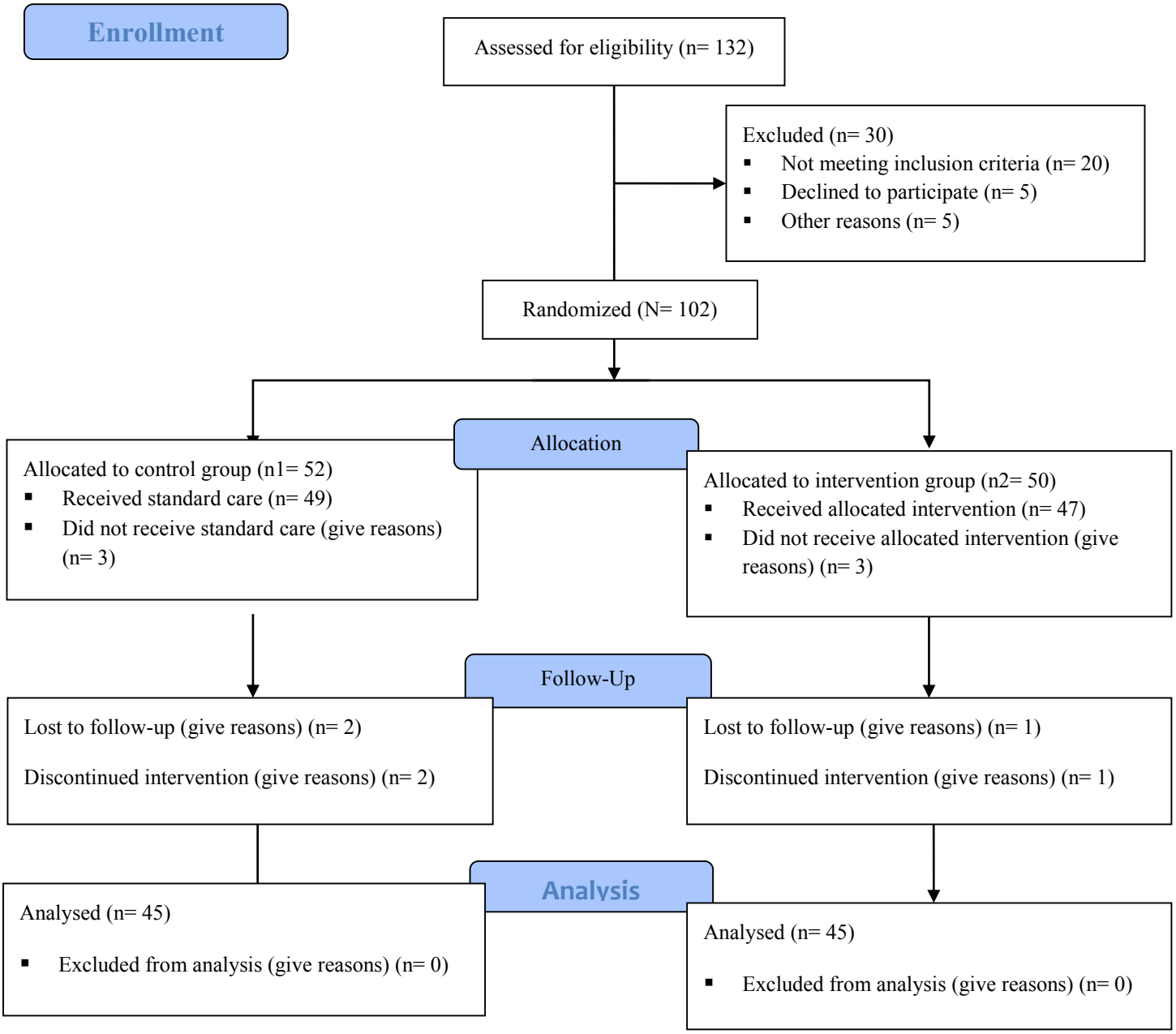
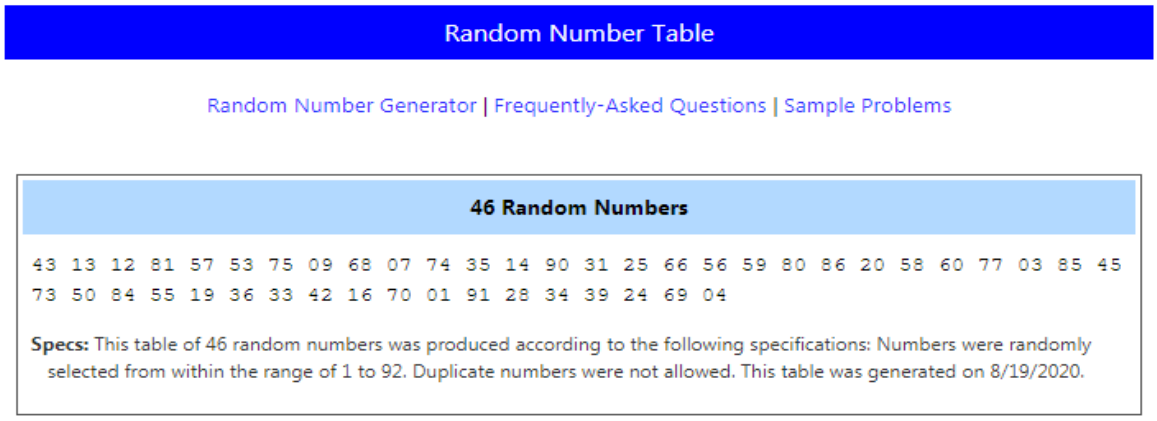
Figure 1. Study Flow Diagram (CONSORT Statement) dummy





Random Number Table

Random Number Generator | Frequently-Asked Questions | Sample Problems

46 Random Numbers

43 13 12 81 57 53 75 09 68 07 74 35 14 90 31 25 66 56 59 80 86 20 58 60 77 03 85 45
73 50 84 55 19 36 33 42 16 70 01 91 28 34 39 24 69 04

Specs: This table of 46 random numbers was produced according to the following specifications: Numbers were randomly selected from within the range of 1 to 92. Duplicate numbers were not allowed. This table was generated on 8/19/2020.

Figure 1: Random generated numbers of intervention group

Box 1: inclusion and exclusion criteria

Inclusion criteria

- Confirmed SCI diagnosis by computed tomography or magnetic resonance report.
- ASIA: A, B, and C
- Age between 18 and 65 years old.
- Stable medical condition.
- Time elapsed after SCI is not more than 6 months.
- Minimum time of stay in inpatient rehabilitation unit is six weeks.
- Active involvement in rehabilitation program.
- Sufficient comprehension (read/write) of the Arabic language.

Exclusion criteria

- Unconfirmed diagnosis.
- Patients who have communication and/or cognitive disorders such as global aphasia and memory deficit.
- Patients with disturbed level of awareness such as coma or lethargy.
- Time elapsed since SCI is more than 6 months.
- ASIA: D and E
- Unstable medical condition.
- Patients who have other cause(s) of disability in addition to SCI such as stroke or amputation.
- Age less than 18 or more than 65 years old.
- Time of stay in inpatient rehabilitation unit is less than six weeks.
- Inactive involvement in rehabilitation program.
- Patients with a progressive disease or a psychiatric condition that would interfere with active participation in rehabilitation program.
- Patients with cardiovascular contraindications.
- Persons who become walking ambulatory during the inpatient period.
- Persons with complete tetraplegia C4 or above.
- Persons on mechanical ventilator.