CHAPTER - 3

Methods
METHODS

3.1 Introduction

The literature review indicated that mobility disability is highly prevalent and its incidence is on the rise worldwide. Mobility disability in community ranges from simple self-care difficulties to complex psychosocial issues along with environmental demands associated with it. Existing scales could not satisfy the all demands that are required for assessing community mobility. Hence, there is a need to develop a scale which compressively measures mobility disability for the community dwelling individuals. To address this need, the study was conducted in which systematic methods were adopted to develop a comprehensive mobility disability scale. This chapter explains the various phases of the study in developing a mobility disability scale for community dwelling individuals and validating the scale for its psychometric properties.

3.2 Objectives of the study:

- The objectives of the study were to develop a comprehensive scale which measure mobility disability in community dwelling individuals under the primary domains and
- To validate the developed scale for
  - Content validity
  - Reliability
  - Concurrent validity and
  - Responsiveness

The chapter III explains the various phases of the study to meet the above mentioned objectives. The study protocol was submitted to the Institutional Ethical
Committee of Kasturba Hospital, Manipal and approval to conduct the study was obtained prior to onset (Appendix 1). The seven phases of the study under which methods are discussed are shown in the following figure.

![Figure 3.1: Phases of the study](image)

Figure 3.1: Phases of the study
3.3: Generation of domains and items

3.3.1 Aim: The aim of this phase of study was to generate the domains and items related to mobility disability in community dwelling using literature search and direct patient interviews.

3.3.2 Literature search: English language literature was searched in PubMed, ProQest, MD Consult, Cochrane Library and EbscoHost databases in the time frame between January 1980 and December 2007. The key words used were community mobility, mobility disability, items of mobility, domains of mobility, dimensions of mobility, mobility disability scales, and mobility disability questionnaire. Age filters were used to restrict the scales and questionnaire for people above nineteen years.

3.3.3 Procedure for literature search: Critical evaluation of scales and questionnaire obtained by the above mentioned search strategy was done to identify the domains and items of mobility disability relevant to the community dwelling individuals. The domains relevant to assess mobility disability in community were identified from the literature and documented. The items identified from the literature were compiled and used for the next stage of item generation including patients with mobility disability.

3.3.4 Sample for direct patient interviews: A community survey was conducted for identifying patients with chronic mobility disability with the help of anganwadi workers in the Udupi district. The anganwadi workers were initially explained about the aims and objectives of the study. They were made aware of the type
and number of patients required and was asked to inform about the same to the investigator. The patients identified by the anganwadi workers were approached individually in their house and their medical records were verified. After verification of their mobility impairments, they were explained about the purpose of the study and informed consent was obtained to participate in the study. The patients were selected with wide range of mobility impairments with the onset duration of more than six months.

3.3.5 **Sample size**: Twenty patients

3.3.6 **Procedure for direct patient interviews**: For direct interviews, all the selected twenty patients were approached in person at home by the principle investigator and the data was collected. These patients were asked to generate the items that were relevant to assess the mobility disability in community. First, the patients were asked to mention different items related to mobility disability that they feel important to be included in the pool. Patients were motivated to fill maximum number of items which they feel appropriate based on their experience. Second, the patients were given the item pool identified from the literature and were asked to add more items which was not mentioned in the literature. This procedure was chosen to yield maximum number of items, which the patients felt that need to be in the scale. The response sheet used for the generation of items by patient interviews was given in appendix 2. After generation of items from the literature and interviews, the items were pooled together and corrected for the duplicates.

3.3.7 **Data analysis**: Descriptive statistics was used to summarize the demographic characteristics of patients and to describe the items generated using literature and interviews.
3.4: Grouping of items in domains and content validation

3.4.1 Aim: The aim of this phase of the study was to group the items generated under the domains identified related to mobility disability and content validate the same for the degree of its relevance in the scale.

3.4.2 Grouping the items under domains: After generation of items by literature search and patient interviews, the items were grouped under the domains identified. First, the items which were closely related in function were identified and grouped. Similarity in activity was considered to group the items together. This is followed by the placing the grouped items under the relevant domain generated. It was ensured that all the items were included under any one of the domains identified.

3.4.3 Content validation: The grouping of items under the domains was followed by its content validation by the panel of experts.

3.4.3.1 Sample: The expert panel consisted of health professions who were involved in rehabilitation of patients with mobility disability. Experts were chosen from the various fields of community based rehabilitation team who visit patient homes for providing rehabilitation services. The experts were identified from the community medicine department of Kasturba Medical College, Manipal. The department was approached and the physician in-charge was requested to provide the details of experts who were part of community rehabilitation team providing the services at the community level. The experts were contacted individually and explained about the purpose of the study seeking consent to participate in this phase of content validation.
3.4.3.2 Sample size: Ten

3.4.3.3 Procedure: All the experts identified were given an information letter explaining the purpose of the study along with the consent form. After the experts gave their consent, an appointment date and time was obtained to meet them in person for the content validation. On the appointment date, the content validation form with the list of domains and items generated was given to the experts. They were asked to judge each item and domain based on its content, relevance, simplicity, clarity and ambiguity. Experts based on their judgement, marked the items and domains as relevant (need to be in the scale) or not relevant (need to be excluded).

Percentage level of agreement between experts was used to evaluate the content validity of items and domains. The criteria to include the items and domains were fixed at 70% i.e, the items and domain will be included only if seven or more experts score it as relevant. The filled content validation forms were received from the experts and the data was compiled and analysed. The items and domains were accepted, modified or deleted based on the level of agreement between experts.

Experts were also requested to provide comments or suggestions regarding the items, domains and the fit of items under the domains. The comments were discussed and analysed with the individual experts and clarifications were done. Further individual meetings with experts were also conducted to clarify the issues raised and collect necessary explanations. The consensus was obtained with all the experts regarding the fit of items under
domains prior to drafting the scale. The consent form and the response sheet used for the content validation are given in appendix 3.

3.4.3.4 Data analysis: Descriptive statistics was used to summarize the demographic characteristics of experts and the percentage was used to report the agreement of experts for each item and domain in the scale.
PHASE III

3.5: Scale drafting with scoring criteria

3.5.1 Aim: The aim of this phase of study was to draft a scale using the items and domains generated along with the scoring criteria.

3.5.2 Scale drafting: The scale drafting includes operational defining of each domain and the items under the domain. The definition of item include multiple sub components related to the activity and the individual must perform all these components to achieve the maximum score for the respective item. The operational definitions for each domain and the items in the scale are explained below.

Domain: Self-care

This domain includes the items which primarily involve the routine activities related to the self-care abilities of the individuals. These items were considered relevant for the all the individuals living in home. The items under these domains and their explanations are as follows

Wearing footwear yourself: This involves the positioning of foot according to footwear, inserting the foot and adjusting the strap/loop inside the feet independently.

Eating yourself: This involves stabilising the plate, bringing food to mouth, chewing and swallowing independently.

Dressing yourself: This involves picking up the dress, inserting the torso and limbs, and adjusting the dress on the body for upper body dressing, while for
lower body dressing it includes holding the dress in standing, inserting one leg at a time by stabilising with the opposite leg or tie the dress around the waist.

*Buttoning your dress (shirt/trousers):* This includes the ability to button, hook or zip the upper body dress like shirt and lower body dress like trousers.

*Shaving yourself:* This includes the ability to use the razor in one hand, stabilising with other hand and shave or trim the facial hair.

*Combing yourself:* *This includes the ability to hold the comb in hand and groom* the hair appropriately as premorbid independently.

*Going to toilet:* This involves moving from the living room or bedroom to the toilet, using the toilet, wash the hands and legs and come back independently

*Bathing yourself:* This includes the ability of person to reach bathroom, take bath (including application of soap), wipe the body clean and come back from the bathroom independently.

*Brushing your teeth:* This includes the ability of person to hold brush, apply paste, brush teeth and clean the mouth independently

*Squatting in the toilet:* This includes the ability of the person to assume squatting position in the toilet independently

*Getting up from squatting position in the toilet:* This includes the ability of person to get up from the squatting position in the toilet independently
Domain: Ambulation

This domain includes the items involving moving from one place to other means of walking or wheelchair

Walking household: This includes the ability of individual to walk inside the house for a minimum distance of six meters independently as in premorbid status.

Walking in community: This includes the ability of individual to walk outside the perimeter of house for a distance of minimum 100 meters independently

Wheelchair household: This includes the ability of individual to propel the wheelchair by self, inside the house for a minimum distance of six meters independently.

Wheelchair community: This includes the ability of individual to propel the wheelchair by self, outside the perimeter of house for a distance of minimum 100 meters independently.

Riding Tricycle: This includes the ability of individual to ride the tricycle outside the house for a distance of minimum 100 meters independently

Domain: Ambient conditions

This domain includes items which require the ability to perform in conditions which are familiar but challenging in terms of narrow space, low light level etc.

Walking or moving around in wet floor: This includes the ability of person to move around in a wet floor like in a bath area or toilet safely without any help.
**Walking in rain:** This includes the ability of person to walk outdoor while raining with an umbrella for the necessary activities independently

**Walking at night:** This item requires the ability to walk at night or low light areas safely without losing balance independently

**Going to smaller rooms:** This item requires the ability of individual to enter inside the space constrained areas like pooja room, kitchen etc independently

**Going to crowded places:** This item requires the ability of individual to walk or go in wheelchair and safely negotiate the crowd in places like market, temple etc.

**Domain:** Attentional demands

This domain includes the items which additionally demands the cognitive ability to perform an motor activity

**Balance while crossing roads:** This includes the ability of individual to perform the dual task of balancing while crossing the roads safe and independently.

**Walking while talking:** This includes the ability of individual to speak into phone or other person by looking at face while walking without compromising on speed of walking.

**Reacting to traffic lights:** This includes the ability of individual to react appropriately with adequate speed to traffic light signals (i.e. stop with red light, or move with green light) while riding or driving the vehicles.
Domain: Postural transitions

This domain includes the items which require the ability of individual to change or move his posture form one position to other while performing activities.

Rolling in Bed: This includes the ability of individual to turn the body from supine lying to side lying position on either side without holding on to the railings of bed.

Getting up from bed: This includes the ability of individual to sit up from lying position in the bed without using railings or any other support.

Sitting on a chair or toilet seat: This includes the ability of individual to maintain the sitting position for 10 to 15 minutes without support on a chair or the toilet seat

Stand up from sitting position: This includes the ability of individual to stand up from the sitting position independently without using the arm rest in a chair or from bed.

Maintain standing: This includes the ability of individual to maintain standing position independently without support for 15 minutes.

Turning while walking: This includes the ability of individual to turn 90 degrees (towards right or left) while walking.

Bend down and pick up objects from floor: This includes the ability of individual to bend down to pick up objects lying on the floor quickly, safely and independently.

Floor sitting: This includes the ability of individual to sit on the floor cross legged and get up from the position independently.
**Domain: Terrain characteristics**

This domain includes the items, which requires the ability of individual to negotiate different types of terrain to perform their activities of daily living.

*Walking uneven surface:* This item includes the ability of individual to walk up and down the slope surfaces like ramp of minimum 10 to 15 meters without human support or railings as per the premorbid status.

*Climbing stairs:* This item includes the ability of individual to climb up and down one flight of stairs of 3 to 5 steps without human support or railings at the premorbid speed.

*Crossing or avoiding the obstacles:* This item includes the ability of individuals to safely negotiate the obstacles such as thresholds or dividers inside the house or stones in the road by crossing or avoiding those without any assistance.

**Domain: IADL**

This domain includes items which require the instruments to perform the activities, considered important for daily living

*Writing/signing:* Writing includes the ability of individual to write fast and legibly as before (similar to premorbid status) using pen in the dominant hand and signing includes the ability to sign as before using pen in the dominant hand.

*Shopping:* This item requires the ability of individual to visit market, buy the vegetables or groceries from market, carry the objects or goods in hand and reach the house independently.
**Cooking:** This includes the ability of individual to involve in cleaning/cutting vegetables, carrying cooking utensils, placing those on the stove, igniting the stove, stirring or frying the food independently.

**Gardening:** This includes the ability of individual to water the plants using watering can or pipe, pruning, weeding, growing plants and plucking flowers.

**Using mobile or fixed phone:** This includes the ability of individual to pick up the phone/mobile, dial the required number, attend the call, hold the receiver or mobile in hand while speaking and replacing the receiver on the phone or the mobile. This also includes the ability of individual to type the text and read the messages in the mobile as per premorbid status.

**Using computer:** This includes the ability of individual to switch on the computer, use key board to type the text, mouse to select and scroll the pages and shutdown the computer.

**Manipulating objects in hand like door knob:** This item includes the ability of individual to use key and door knob or handle to open and close the door as per the premorbid speed.

**Holding or carry objects while walking:** This item includes the ability of individual to hold or carry the objects (of load up to one kilogram) in the hand and walk independently for a distance of half a kilometre.

**Domain: Transport**

This domain includes the items, which requires the ability of individual to travel from one place to other using different means of transport.
Riding/ driving of vehicles: This item includes the ability of individual to ride the two wheelers like bicycle or motor cycle or drive the four wheelers like car for a distance of minimum one or five kilometres independently. This also includes the ability to position the vehicle, start, pedal or accelerate, apply break, stop and park the vehicle in the required place.

Using public transport: This item includes the ability of individual to board the bus/train, occupy the space allotted and get out of the vehicle without any assistance.

Travelling by private transport: This item includes the ability of individual to get inside the private vehicles like auto or taxi, sit in the vehicle and get out of the vehicle without any assistance.

Domain: Psychosocial

This domain includes the items which assess the impact of mobility disability in the psychosocial issues.

Fear of fall while walking: This item assesses the frequency of fearfulness experienced by the individual while walking inside and/or outside the house.

Feeling depressed: This item assesses the frequency of feeling of sadness experienced by the individual because of mobility problems.

Disturbance in family role: This item assesses the frequency of feeling about the disturbance in family role performance by the individual because of mobility problems.
Decreased motivation: This item assesses the frequency of feeling decreased motivational level while performing the activities of daily living by the individual due to mobility problems.

Feel “dependent”: This item assesses the frequency of feeling dependent by the individual for his/ her personal care due to mobility problems.

Decreased interest in functions: This item assesses the frequency of showing or feeling decreased interest by the individual in participating in social, religious and other functions due to mobility problems.

Feel tired: This item assesses the frequency of feeling exhausted and tired while carrying out simple tasks due to mobility problems.

Job: This item assesses the frequency of feeling the worthlessness due to inability of performing job as in the premorbid status.

Pain: This item assesses the frequency of feeling pain while performing the routine activities of daily living because of mobility problems.

3.5.3 Scoring criterion: The scoring criteria for the scale was formed to represent the mobility disability on a 5-point scale ranging from 0 to 4, where 0 is no disability and 4 is 100% or complete disability. The middle scores represent 1 (25% disability), 2 (50% disability) and 3 (75% disability). The scoring options were designed according to the items under each domain however the grading of disability across each domains followed similar pattern i.e. no disability to complete disability on a five point scale. Following this, the draft of the scale was formed with the scoring criteria and used for pilot testing.
PHASE IV

3.6 Pilot testing

3.6.1 Aim: The aim of this phase was to pilot test the scale draft in patients with mobility disability to assess the comprehensibility, acceptability, complexity, administrative difficulties, frequency of responses and sequence of domain or item arrangements in the scale.

3.6.2 Study design: Cross sectional study

3.6.3 Sample: Patients with mobility disability were identified from the community through survey with the help of health care team visiting patient homes in the Udupi district. The patients identified in the community were approached individually in their houses. They were explained about the purpose of the study and their medical records were verified for their mobility impairments. The patients who had mobility impairments and those who were willing to participate were screened for the inclusion and exclusion criteria to be included in the study. A written informed consent was obtained from the patients who were included in the study.

3.6.4 Inclusion criteria

- Patients with mobility deficits living in home
- Patients with the onset duration of mobility deficits more than three months
- Patients who were able to understand and follow instructions

3.6.5 Exclusion criteria

- Patients with coexisting acute illness who require immediate management

3.6.6 Sample Size: Thirty five patients
3.6.7 Procedure: The patients included for the study following screening were interviewed in person to evaluate mobility disability using the scale. The details of the patients regarding age, gender, condition and duration of the condition were documented.

In the interview, patients were asked, whether they were able to perform the particular item in the scale. If they answered yes, they were asked to compare it with the premorbid state in terms of speed and quality of the performance. If the patient had said that, there was no difference between premorbid and current status, then, they were scored 0 or no disability for the particular item. If they had said that there was some difference between current and premorbid statuses, then they were scored as 1 or to have 25% disability for the particular item.

In the interview, when the patient reported that they have difficulty to perform a particular item, they were asked, whether they needed human support for performing the activity. If they answered yes, they were also asked to quantify the level of human support. If the support was given only for the initiation and/or termination of the activity, they were scored 3, i.e. 75% disability whereas, if the support was given throughout most of the activity, they were scored 4, i.e. 100% disability. If the patients had answered no, i.e. they do not need human support but require assistive devices or modification of activity then, they were scored 2 or to have 50% disability.

When patients were unable to perform an item due to the mobility problem, they were scored as 4, i.e. complete disability, whereas if they were not used to perform the item in the premorbid phase as well or if the item was irrelevant for them, then the particular item was not scored and marked as not applicable.
Adequate explanations were given to make the patient understand the item. When required, examples of situations were provided to make the patient understand the scoring options. For example, to wear footwear, when patients said it was difficult but does not require human support, then they were asked whether they need to keep the footwear near the wall to make it easier for wearing or they need to sit on a chair for the same. If patient answers yes for any of these situations, then he/she was scored 2 i.e. 50% disability. In situations, where the patient could perform independently in most circumstances with or without assistive devices, but requires human assistance occasionally, then the highest score (human support) was recorded. The flow chart for scoring the items in the scale is given in the following figure 3.2.

Figure 3.2: Flowchart for scoring items in the scale except psychosocial domain
All the items in the particular domain were completed before moving to next domain. Whenever required and possible, patients were allowed to perform the activity once to decide the scoring option, if there was an ambiguity in scoring. The items in the psychosocial domains were scored in terms of frequency. Privacy of the patient was ensured when scoring the items under this domain to prevent any proxy influence from the family members. However the family members were consulted to decide the scoring for other items, especially when the patients reported the need of assistive device, modification of activity or human support in other domains.

The time taken to complete each assessment and frequency of responses was noted to determine the administrative difficulties associated with the scale. The scoring criteria were evaluated based on the frequency of scoring options for each item in the scale. Based on the ability of the patients to understand the item, the relevance of item to the patient population and the frequency of responses for each item, the scale was subjected to modification. It was decided to eliminate the item, if the frequency of response was less than 30% for the item. The modification of items and scoring criteria were made after discussion with experts involved in the content validation. After the consensus was obtained regarding the domains, items and its arrangement in the scale, the final scale was formed. This scale with modified items and domains was subjected to the next phase of validation.

3.6.8 Data analysis: Descriptive statistics (Mean, standard deviation and range) was used to summarize the age and duration of conditions of patients' participated in this phase of study. Frequency analysis was done to quantify the number of responses and the scoring for each item. Subjective opinions from the patients and experts were used to modify the items and domains in the scale.
PHASE - V

3.7 Reliability

3.7.1 Aim: The aim of this phase of the study was to determine the internal consistency and test retest reliability of the new scale in patients with mobility disability.

3.7.2 Study design: Cross sectional study design

3.7.3 Study Setting: Patients’ house in the Udupi district and the outpatient department of physiotherapy, Kasturba Hospital, Manipal

3.7.4 Sample: The sample of patients for determining reliability was identified in the community through community survey with the help of social workers and anganwadi workers of the respective primary health centers in the Udupi district. The patients visiting physiotherapy outpatient department of Kasturba hospital, Manipal with chronic mobility disabilities were also included for this phase of study.

3.7.5 Sampling method: Convenience sampling.

3.7.6 Inclusion criteria

- Patients with mobility deficits living in home
- Patients with the onset duration of mobility deficits more than one month
- Patients who were able to understand and follow instructions
- Patients who gave consent for participation in the study

3.7.7 Exclusion criteria

- Patients with coexisting acute illness who require immediate management
3.7.8 Sample size:
Sample size \((n)\) was calculated using the following formula

\[
n = \frac{Z_{\alpha}^2 \sigma^2}{d^2} = 60
\]

Where, \(Z_{\alpha} = 1.96\) (95% CI), \(\sigma = 38\) (SD) and \(d = 10\) (Precision)

3.7.9 Procedure for internal consistency reliability: Patients identified for the study were screened for the inclusion and exclusion criteria. The selected patients were explained about the purpose of the study and informed consent was obtained. The new scale was administered on the patients by the interview method as explained in the previous phase of the study. The tester provided adequate explanation, when the patients did not understand the item and ensured that all the items in the scale were scored. The scores were added to calculate the individual domain as well as the total score of the new scale. These scores were used to analyze the internal consistency of items in the new scale.

3.7.10 Procedure for Test rest reliability: The initial scores of the sixty patients obtained by the above mentioned method was documented. For determining the test retest reliability, the new scale was administered again to the same patients after 5 days but less than 7 days of the initial evaluation. In order to prevent the recall bias of the patients, domains in the scale were rearranged during the second assessment. The scores obtained during the second assessment were also added to calculate the individual domain and total score of the new scale. The scores of both the initial and second assessment were used to determine the test retest reliability of the new scale.
3.7.11 Data analysis: Descriptive statistics was used to summarize the demographic characteristics of the patients. Cronbach’s alpha coefficient was used to analyse the internal consistency of all the items in the mobility disability scale and items under each domain. For the purpose of this study, Cronbach’s alpha ≥ 0.8 was considered as evidence of acceptable internal consistency. Test retest reliability was evaluated using Intra class Correlation Coefficient (ICC). ICC was computed to evaluate the test retest reliability for each domain scores and the total scores. For the purpose of this study, ICC ≥ 0.75 was considered as evidence of acceptable test–retest reliability. The level of significance was set at P ≤ 0.05 for all the statistical analysis.
PHASE - VI

3.8: Concurrent validity

3.8.1 Aim: The aim of this phase of the study was to determine the concurrent validity of the new scale with the existing FIM FAM scale in patients with mobility disability.

3.8.2 Study design: Correlation study design

3.8.3 Study Setting: Patients’ house in the Udupi district and the outpatient department of physiotherapy, Kasturba Hospital, Manipal

3.8.4 Sample: The sample of patients for determining concurrent validity was identified in the community through community survey with the help of social workers and anganwadi workers of the respective primary health centers in the Udupi district. The patients visiting physiotherapy outpatient department of Kasturba hospital, Manipal with chronic mobility disabilities were also included for this phase of study.

3.8.5 Sampling method: Convenience sampling

3.8.6 Inclusion criteria

- Patients with mobility deficits living in home
- Patients with the onset duration of mobility deficits more than one month
- Patients who were able to understand and follow instructions
- Patients who gave consent for participation in the study

3.8.7 Exclusion criteria

- Patients with coexisting acute illness who require immediate management
3.8.8 Sample size:

Sample size was calculated using the following correlation formula

\[ n = \frac{Z_\alpha + Z_\beta^2 + 3}{[C \cdot r]^2} \approx 52 \quad \text{Where} \quad C(r) = \frac{1}{2} \log_e \frac{1+r}{1-r} \]

\[ Z_\alpha = 1.96 \ (95\% \ CI), \ Z_\beta = 1.28 \ (90\% \ power) \ & \ r = 0.6 \ (correlation \ coefficient) \]

3.8.9 Procedure: Patients identified for the study were screened for the inclusion and exclusion criteria. The selected subjects were explained about the purpose of the study and informed consent was obtained. The new scale was administered on the patients who had mobility deficits by the interview method as explained in the previous phases of the study. The tester ensured that all the items in the scale were scored and documented. After the documentation, the Functional Independence Measure and Functional Assessment Measure (FIM FAM) scales were administered. The FIM FAM scale was administered as per the procedure guidelines given by the authors of these scales.

In order to prevent sequence bias, the new scale and FIM FAM scales were used alternately for the first evaluation followed by the other scale, respectively. Thus, 26 patients were evaluated initially with the mobility disability scale and the remaining 26 patients were evaluated initially by the FIM FAM scales. The item scores of each domain were combined to calculate the domain and total scores for the new scale and FIM FAM scales. Concurrent validity was determined by correlating the domain and total scores of the new scale with the relevant domain and total scores of Functional Independence Measure (FIM) and Functional Assessment Measure (FAM) scales.
3.8.10 Data analysis: Descriptive statistics was used to summarize the demographic characteristics of the patients. The Spearman’s Rank correlation coefficient was used to analyse the correlation between domains and total scores of the new scale and FIM FAM scales to determine the concurrent validity. The level of significance was fixed at $p \leq 0.05$ and the correlation coefficient ($r$) > 0.6 was considered to be an acceptable correlation for this study.
PHASE - VII

3.9 Responsiveness

3.9.1 Aim: The aim of this phase of the study was to determine the responsiveness or the ability of the scale to identify the change between two time sequences which is supposed to have produced a change. In our study, the responsiveness was evaluated by using the new scale before and after treatment in patients with stroke.

3.9.2 Study design: Single group pretest- posttest design

3.9.3 Study Setting: Stroke clinic in Udyavara-Udupi district, Neurorehabilitation Unit and the outpatient department of physiotherapy, Kasturba Hospital, Manipal

3.9.4 Sample: The study sample consisted of the patients diagnosed with first stroke attending stroke clinic, Udyavara for physiotherapy services and those referred for physiotherapy in Kasturba Hospital, Manipal.

3.9.5 Sampling method: Convenience sampling

3.9.6 Inclusion criteria

- Patients with first onset of stroke
- Patients with the onset duration of stroke more than one month
- Patients who were able to understand and communicate
- Patients living in the home post stroke for more than two weeks

3.9.7 Exclusion criteria

- Patients with coexisting acute illness who require immediate management
3.9.8 Sample size:

Sample size (n) was calculated using the following comparison of means formula

\[ n = \frac{Z^2 \sigma^2}{d^2} = 58 \]

Where, \( Z\alpha = 1.96 \) (95% CI), \( \Sigma = 35 \) (SD) and \( d = 10 \) (Anticipated difference)

3.9.9 Procedure: Patients diagnosed with first stroke from the above mentioned setting were screened for the inclusion criteria. The selected subjects were explained about the study and the informed consent was obtained to participate in the study. Demographic characteristics, side of affection and duration of stroke were documented. The baseline assessment of the selected patients was done using the new scale after which they were given physiotherapy treatment which was tailor-made according to the stage of stroke.

The physiotherapy treatment consists of active and passive exercises for affected upper and lower limb, facilitatory techniques to improve voluntary control and inhibitory techniques to reduce spasticity. Functional re-education including bridging, transition training for lying to turning, coming to sitting and sitting to standing was given. Weight bearing to affected upper and lower limb, weight shifting to both limbs were given in front of parallel bar. Balance and ambulation training were given to improve walking ability in both level and uneven surfaces.

Assistive aids like elbow crutch or cane were prescribed for the required patients. Stair negotiation training was given for the patients who could walk with minimal support in level surface. Patients were allowed to undergo additional treatments in the form of occupational therapy, Ayurveda etc as per their choice; however they were instructed not to skip the physiotherapy protocol advised.
Supervised treatment was given for two days per week for all the patients. Patients were taught home program and advised to perform these exercises every day. The exercises were reviewed during the successive supervised sessions. The treatment was given one hour per day for a period of eight weeks after which patients were re-evaluated using the new scale. The pre and post treatment scores of the new scale were analysed to determine the responsiveness of the scale.

All the patients were asked to rate their recovery following eight weeks of treatment using global rating of change scale (GRCS). These scales are designed to quantify the patients’ improvement or deterioration over time. The patients were asked to assess his/her current mobility status, recall the status before treatment and then calculate the difference between the two time points. The magnitude of this difference is then scored on a numerical value ranging from 0 to 4, where 0 is no change and 4 is completely recovered. These GRCS scores rated by the patients were correlated with the change scores of new scale.

The GRCS scores were used to divide the stroke patients into two groups as those who perceived recovery following treatment and those who did not. The difference in the mean change scores of new scale between these two groups was calculated as the minimal clinical important difference (MCID).

3.9.10 Data analysis: Descriptive statistics was used to summarize the demographic characteristics of the patients. Wilcoxon Signed Rank test was used to analyse pre and post treatment scores of the new scale. The GRCS scores were correlated with the change scores of the new scale using Spearman’s Rank correlation coefficient. The level of significance was fixed at p<0.05 for the analyses.