

Study Protocol

The Relationship between Upper Extremity Motor Function and Oral Hygiene among Stroke Survivors: Study Protocol for a Mixed-Method Design

ABSTRACT

Background: Stroke is emerging as a leading cause of preventable death and disability in adults in many developing countries. One important aspect of self-care is the oral health care. Individuals who have suffered stroke may have difficulty to independently complete the needed Oral Health Care tasks and this can lead to the development of dental caries and periodontal diseases. In addition to that, the saliva may also become populated by high numbers of bacteria, and when these are aspirated, pneumonia or systemic infection can result.

Objective: To investigate the relationship between upper extremity motor function and the state of oral hygiene in stroke survivors.

Methods: A two phase explanatory sequential mixed-method design is proposed to examine the relationship between upper extremity motor function and oral hygiene of stroke survivors. The first phase consists of the collection and analysis of quantitative data in order to address the study's research questions. The second involves the collection and analysis of qualitative data through focus group discussions with some stroke survivors and an in-depth interview of physiotherapists and dentists to understand the views of these professionals on the problem.

Results: Research setting selection and preparation, instruments selection and research assistants training has been completed. Data collection is in progress.

Conclusion: This description of the study methods will be useful for clinicians and researchers in planning and implementing studies of this kind.

KEYWORDS: *upper extremity, upper limb, oral hygiene, oral health, stroke*

INTRODUCTION

Cardiovascular diseases contribute largely to Non-Communicable Diseases (NCDs). Approximately seventeen million deaths occur annually due to cardiovascular diseases (including stroke) worldwide¹. While these conditions were previously seen to be unpopular in developing countries such as the sub-Saharan Africa (SSA), it is now acknowledged that stroke is a major cause of death in low-income and middle-income countries². The burden of stroke is rapidly escalating, with the burden of the brunt more in poor than rich communities³.

Annually about fifteen million people worldwide are affected by stroke⁴, and an estimated 80% of all deaths from stroke will occur in low-income and middle-income countries⁵ and about five million of the global stroke population become permanently disabled⁴. Stroke is emerging as a leading cause of preventable death and disability in adults in many developing countries. In SSA, stroke occurs at much earlier ages, resulting in greater number of years of potential life lost⁶. The high social and economic burden of stroke calls for effective strategies for prevention, treatment, and rehabilitation in SSA⁶.

Oral health care is considered as one crucial aspect of self-care is the oral health care. Individuals who have suffered stroke may have difficulty to independently complete the needed oral health care tasks⁴, and this can lead to the development of dental caries and periodontal diseases. In addition to that, the

saliva may also become populated by high numbers of bacteria, and when these are aspirated, pneumonia or systemic infection can result⁴. Plaque and other bacteria build up can also contribute to halitosis and oral infections⁷. A previous study has identified poor oral hygiene among stroke survivors to be a cause of pneumonia, systemic infection, endocarditis and even death⁴. Both therapists and family caregivers of stroke patients are inclined towards the primary problems of these individuals such as motor deficits, in- coordination and compromised cognition while not giving much attention to other secondary problems such as Oral Health Care, which may be inadequate, leading to other additional health concerns⁸.

According to the stroke foundation⁹, rehabilitation of stroke patient should be given a holistic and purpose driven approach. As such limiting rehabilitation of stroke survivors to physical functioning with little or no focus on certain important self care needs such as oral health negates the principle of holistic rehabilitation approach. Obviously, achieving better physical function post stroke may contribute positively to improved self care. However, little is known on the impact of reduced upper extremity motor function on oral hygiene among stroke survivors. Exploring the contribution of poor upper extremity motor function in oral health among stroke survivors will expand the focus of rehabilitation particularly on assessing and monitoring the progress of oral health from the outset of rehabilitation programme. This will not be achieved until the extent of the problem is well appreciated.

This study is therefore designed to investigate the relationship between upper extremity motor function and the state of oral hygiene in stroke survivors.

The main aim of this study is to determine the influence of upper extremity motor function on oral hygiene of stroke survivors.

Objectives of the study

The study objectives include determining:

1. Prevalence of poor oral hygiene among stroke survivors.
2. The association between upper extremity motor function and oral hygiene status of stroke survivors
3. The association between arm dominance and oral hygiene of stroke survivors.
4. The association between duration of stroke and oral hygiene status.
5. The influence of gender on oral hygiene status in stroke survivors.
6. The influence of socio-economic status on oral hygiene status of stroke survivors.
7. The influence of age on oral hygiene status of stroke survivors.
8. The association between level of education and oral hygiene status of stroke survivors.
9. The impact of oral health on the QoL of stroke survivors
10. The perception of stroke survivors and their health care providers about oral health post stroke

This paper describes the study protocol.

METHODOLOGY

DESIGN

An explanatory sequential mixed- method design (Figure 1) was developed to examine the relationship between upper extremity motor function and oral hygiene of stroke survivors. This design starts with collection and analysis of quantitative data (first phase) which has the priority for addressing the study's research questions. The first phase is then followed by the subsequent collection and analysis of qualitative data (second phase), this consist of focus group discussions with some stroke survivors and an in-depth interview of Physiotherapists and dentists to understand the views of these professionals on the problem.

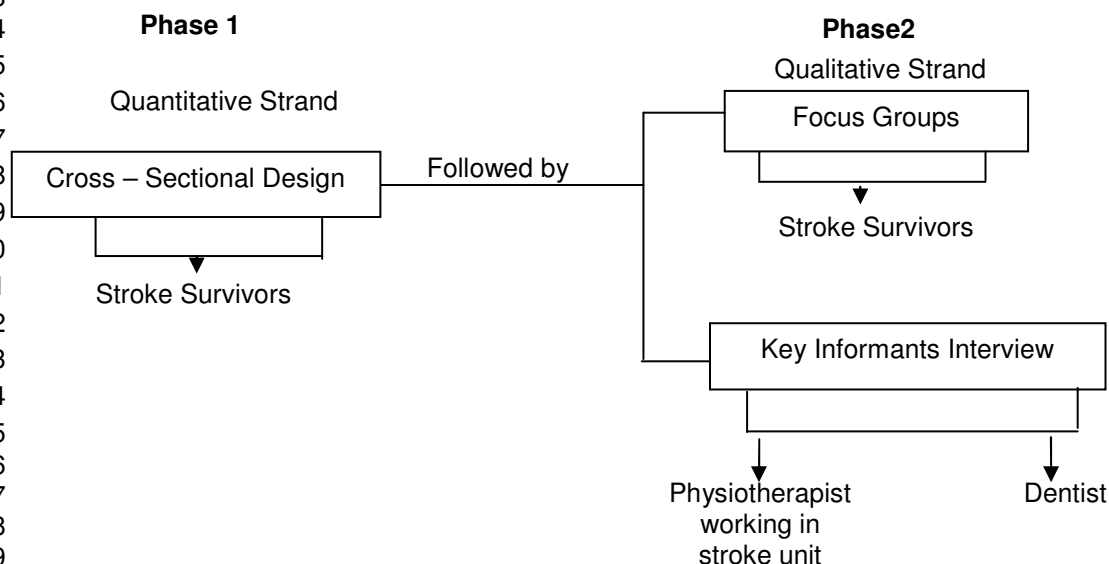


Figure 1 Study design

Setting

Participants will be recruited from National Hospital Abuja (NHA) Nigeria, a Federal Government owned Health Institution, situated in the Federal Capital Territory (FCT) Abuja. It is a 200-bed capacity hospital that receives patients from all over Nigeria¹⁰. It is the second biggest hospital in the Federal capital territory and as such, clientele capacity for a host of medical conditions including stroke is large. Patients' characteristics are ethnically diverse in this hospital.

Participants

All stroke patients referred for physiotherapy in NHA will be considered for eligibility to participate in this study. Participants who meet the inclusion criteria of being diagnose with first episode of unilateral stroke by a physician based on World Health Organization¹¹ definition of stroke which reads: "rapidly developing clinical signs of focal (or global) disturbance of cerebral function, with symptoms lasting 24 hours or longer or leading to death, with no apparent cause other than of vascular origin"; ≥18 years of age; of onset ≥14 days; of sufficient cognition to participate (having a score of ≥15 points cognitive-log); willing to participate and signing a written informed consent, will be included in the study.

Participants will be excluded if they: have facial palsy; currently smoke or quit smoking not more than 3months ago; lost at least half of their teeth; present mental instability or receptive aphasia, being completely unconscious, irritable or medically unstable.

Sample Size and Sampling Technique

Using the formula for cross-sectional study $(n = Z^2_{\alpha/2} p(1-P)/d^2)$, frequency of stroke of 4.0% ¹² and at $\alpha = 0.05$, a total sample size of 59 was generated. A total of 60 participants will be sampled through convenience sampling technique. As a non-invasive observational study, it is expected that there will be limited chance for dropout following consent, for which the targeted sample will hopefully be achieved following recruitment.

135 **Table 1: Data Collection Instruments**
136

Scales Modified (MAS)	Ashworth	Scale	Description
			Is selected to measure a common clinical structural affection in stroke of spasticity. The scale is used to measure spasticity in patients with lesions of the central nervous system; it tests the resistance to passive movement about a joint with varying degrees of velocity. It is an ordinal scale, with six possible scores ranging from 0 (No increase in muscle tone) to 4 (Affected part(s) rigid in flexion or extension), it has an additional score of 1+. The tool has an excellent inter-rater and test-retest reliability ($\kappa > 0.84$), in stroke population ¹³ also an excellent convergent validity with Fugl-meyer ($r = 0.94$), Box and block test ($r = 0.83$), and grip strength ($r = 0.86$) were reported in stroke survivors ¹⁴ .
Stroke Rehabilitation Assessment of Movement Measure (STREAM)			Was designed for use by Physical Therapist to provide quantitative evaluation of motor functioning for stroke patients. It is used to measure functional mobility of the extremities in stroke survivors. The scale is composed of 30 items distributed across 3 domains: upper-limb movements (scored on a 3-point ordinal scale), lower-limb movements (scored on a 3-point ordinal scale) and basic mobility items (scored on a 4-point ordinal scale). It was reported to have an excellent test-retest reliability ($ICC = 0.96$), and excellent internal consistency; mobility subscale ($\alpha = 0.965$), limb subscales ($\alpha = 0.979$) ¹⁵ and overall STREAM scores ($\alpha = 0.984$) ¹⁶ .
Action Research Arm Test (ARAT)			The ARAT is a performance based tool with 19 item scale divided into four subscales: grasp, grip, pinch, and gross movement. The items within each subscale are arranged on a 4-point ordinal scale ranging from 0 to 3, with 3 indicating normal performance on each item. The maximum score on the ARAT is 57 points (possible range is 0-57). There are four subtests: Grasp, Grip, Pinch, and Gross Movement. Items in each are ordered so that: • if the subject passes the first, no more need to be administered and he scores top marks for that subtest; • if the subject fails the first <i>and</i> fails the second, he scores zero, and again no more tests need to be performed in that subtest; • otherwise he needs to complete all tasks within the subtest It has a good test-retest reliability for both chronic and acute stroke, $ICC = 0.963$¹⁷, internal consistency $\alpha = 0.985$¹⁸ and construct validity in relation to the arm section of Fugl Meyer, $ICC = 0.925$¹⁷. An excellent correlation was reported ($r = 0.94$, $p < 0.01$) between ARAT and Arm motor score of the Fugl-meyer¹⁹. Higher score indicate better performance. This scale will be used in this study to test upper extremity function among participants.
Simplified Oral Hygiene Index (OHI-S)			OHI-S is used to measure oral hygiene status; it is composed of the combined Debris Index (DI) and Calculus Index (CI). Each of these indexes, in turn, is based on numerical determinations representing the amount of debris or calculus found on the buccal and lingual surfaces of the preselected tooth. The maxillary and mandibular arches are each composed of three segments; each segment is examined for debris or calculus. Six surfaces examined for OHI-S are selected from four posterior and two anterior teeth. In the posterior portion of the dentition,

usually the first molar but sometimes the second or third molar is examined. The buccal surfaces of the selected upper molars and the lingual surfaces of the selected lower molars are inspected. In the anterior portion of the mouth, the labial surfaces of the upper right and the lower left central incisors are scored. For each individual, the debris scores are totaled and divided by the number of surfaces scored. At least two of the six possible surfaces would be scored and examined for an individual score to be calculated. The same methods are used to obtain the calculus score. The DI and the CI are combined to obtain the OHI-S. The CI and DI values may range from 0 to 3; the OHI-S values from 0 to 6. It is the gold standard for oral hygiene assessment²⁰.

14-item short version Oral Health Impact Profile (OHIP-14)

OHIP-14 is one of the most widely used OHRQoL indicators internationally; it was developed as a shorter version of OHIP-49²¹. This questionnaire asks how problems with your teeth, mouth or dentures may have caused problems in your daily life. It is a self-administered questionnaire in a form of a likert scale, where respondent will choose one of the available options (indicating how often one has had the problem during the last year) in response to the question on the left hand side of the instrument page. The instrument is available in several languages and has been shown to have face and content validity for different populations.^{22,23}

137

138 Data Collection Approaches

139 Quantitative Strand (phase 1)

140 This phase of the study is divided into three sections including the socio-demographic, stroke limitations
141 and oral hygiene constructs. Data for the three sections would be captured by trained Research
142 Assistants (RAs).

143 Four Research Assistants (RAs) will be appointed; two physiotherapists and two dental therapists. The
144 responsibilities of the RAs include recruitment of participants and help in collecting data. The RAs will be
145 trained on specific aspects of their responsibilities prior to the commencement of the study. The
146 Physiotherapists shall collect data on stroke related limitations of the affected upper extremity and the
147 dental therapists will be responsible for assessing the Oral Hygiene Index.

148 Socio-demographic characteristics

149 Socio-demographic characteristics of the participants will be recorded on a researcher questionnaire. The
150 questionnaire would consist of four sections, section A is the socio-demographic data of the participants;
151 Age, Sex, Marital Status, Place Residence, Religion, Tribe, Education, Occupation and Socio-economic
152 status. Section B consists of stroke specific information; duration of stroke, affected side and arm
153 dominance. Section C is information about oral care practice and section D is the oral hygiene index
154 score.

155 Stroke limitation constructs

156 The criterion rehabilitation measures (MAS, STREAM and ARAT) will be used to assess the motor
157 function of the affected upper extremity of the participants. Upper extremity spasticity, mobility and
158 performance are basically the variables to be measured in this construct. In this study, three major upper
159 extremity joints; shoulder, elbow and wrist will be considered for spasticity measurement, all movement

160 that occur in each of these three joints will be assessed for spasticity using the MAS. In each joint the
161 highest MAS score will be recorded.

162 ***Oral hygiene constructs***

163 Oral hygiene status will be assessed simultaneously using the OHI-S and the score will be recorded on
164 the oral hygiene score section of the questionnaire. Also, OHIP-14 will be used to assess how problems
165 with subject's teeth, mouth or dentures may have caused problems in his/her daily life.

166 The quantitative data collection is estimated to last for about 40 minutes with one subject.

167 **Qualitative Strand (phase 2)**

168 ***Summary***

169 Two methods of data collection will be employed in this phase; Focus Group Discussions and in-depth
170 interviews (key informants' interview). Focus Group Discussion of the stroke survivors and individual
171 interviews of experienced physiotherapists working in the stroke unit and dentists will be conducted.

172 ***Focus Groups***

173 Participants will be grouped based on two characteristics; a) duration of stroke, and b) affected side/arm
174 dominance. There will be three groups based on duration of stroke as follows: i) 0-3months, ii) >3months
175 < 6months and iii) ≥ 6months. Each of the three groups will further be divided into two subgroups of; a)
176 those with affectation of dominant upper extremity and b) those with affectation of non-dominant upper
177 extremity. A group will consist of at least six and at most twelve participants, and these include not only
178 those who participated in the quantitative strand of the study, but also other stroke survivors that meet the
179 inclusion criteria. Participants' consent will be sought prior to data collection, and Focus Group Discussion
180 will be audio-recorded for transcription of de-identified verbatim comments and field notes will be taken.
181 Focus groups will be scheduled on a day acceptable to group members and will last for 45-90 minutes.

182 ***Individual interviews***

183 For the purpose of this study, physiotherapist working in the stroke units and dentists are considered as
184 the key informants. Individual interviews will be carried out with six of each of these professionals.
185 Participants in this category should have practice experience of 10 years and above and should be willing
186 to participate. Their opinions, perceptions and experiences about stroke patients seen in the clinic and
187 their oral hygiene status and oral care practices will be sought. The interviews will take place in the
188 participant's place of choice and at their convenient time, and will take at least 10 minutes and at most 30
189 minutes. Each individual interview will be audio-recorded and transcribed for analysis.

190 **Data Management and Analysis**

191 In phase 1 (the quantitative strand), the researchers will assess all quantitative data for completeness. All
192 data will then be cleaned and checked for errors by the chief researcher prior to data analysis. Data
193 recording will be done on Microsoft excel before being exported to Statistical Package for Social Science
194 (SPSS) version 19. Participants' study outcome would be considered using both descriptive and inferential
195 statistics. Participants' socio-demographic data will be described using frequencies, percentages, means
196 and standard deviations as the case may be, if categorical or continuous variable. Z-test would be used to
197 establish the prevalence of oral hygiene among study sample. Pearson coefficient of correlation would be
198 used to establish relationship between upper extremity motor function and oral hygiene status of the
199 participants. Differences in oral hygiene due to hand dominance, and duration of stroke and gender of
200 participants would be determined using Mann Whitney U test, as extended Chi-square would be used to
201 determine same according to age categories, socioeconomic status, and level of education of the

participants. Multiple regression analysis will be performed to determine the most predictor of oral hygiene among demographic characteristics and upper extremity motor function in stroke survivors.

For phase 2, qualitative interviews and focus group discussions will be transcribed for analysis. Field notes will be typed up as Microsoft Word documents. Thematic analysis will be used to analyze the data.

Thematic content Analysis

The thematic content analysis would be used to analyse the qualitative data content in this study based on the work of Morse.²⁴ The author posited four cognitive processes through which thematic content analysis in qualitative research could be conducted. For this study, a manual process of analysis would be used to achieve the processes involved.

To keenly comprehend information in the data, verbatim transcription of audio recordings from the interviews would be performed immediately after each interview; this will give the researcher a sense of understanding of emerging information before proceeding with further interviewing. The researchers will read and re-read the transcripts for all interviews conducted to have a full sense/picture of what is being described by the participants. Transcript of each interview would then be analysed individually via line by line coding. This would allow the researchers to capture the underlying meaning of texts in the transcripts thereby enhancing the understanding of the phenomenon of impact upper extremity motor function on oral health among participants.

Coding would first be done manually for each transcript after which the transcripts would later be arranged into columns on Microsoft word/Excel for analysis; this would enable the researchers to have an easier and quicker comparison of data. Similar descriptions and direct quotes that emerged via line by line analysis of the data would be aggregated to form categories. Thereafter, patterns and relationships that connect the categories would be analysed to form themes. This process would be repeated for all transcripts before cross analysis of all transcripts would be conducted. This will provide for a clear picture of the commonalities amongst transcripts. The researchers would compare the various categories obtained from the analysed data with relevant literature thereby enabling the establishment of links between the study findings and existing theories. All other rules/measures to ensure authenticity such as bracketing, trustworthiness, triangulation consistency and confirmability will be strictly adhered to in managing the data.

Results

Research setting selection and preparation, instruments selection and research assistants training has been completed. Data collection is in progress.

Discussion

Due to its sequela and prevalence, stroke is still a major source of disability. A combination of motor, sensory, perceptual and cognitive deficits often occur after stroke, which in turn cause deficit in Activities of Daily Living (ADL).²⁶ There is compromised motor and cognitive abilities after stroke, which may cause an individual to have impairments in any of the dimensions of oral self-care, and thus limited or unable to perform oral self-care to a satisfactory level. In addition, food can be trapped in the buccal cavity without the patient being aware of it and if optimal brushing is difficult, dental caries and periodontal diseases can occur in addition to the increased bacterial load. Individuals with history of stroke are significantly more likely to seek urgent care for periodontal problems than the general population,⁴ but visits by stroke patients to the dental clinic can be sparse as a result of being house bound, confined mostly to wheelchair, or the inability to climb stairs or to drive.

This study aims to use a cross-sectional and qualitative design with multiple-methods of data collection approaches to determine the influence of upper extremity motor function and socio-demographic characteristics on oral hygiene of stroke survivors and impact of oral health on the QoL of stroke survivors attending the physiotherapy outpatient department of the NHA, Nigeria. This mixed-method approach aims to seek elaboration, enhancement, illustration and clarification of the result from one method with the result from the other method.

Limitations

Some potential limitations with the proposed methods are evident. As it is common with cross-sectional studies, the problem of temporality (possible poor oral hygiene might be there even before the stroke) is a foreseeable challenge. There is possibility of Hawthorne effect in the focus groups and interview methods of data collection as presence of a moderator and interviewer in both scenarios respectively, may influence participant responses or behaviors.

Conclusion

This study will be carried out at the NHA, a Federal Government owned Health Institution situated in the Federal Capital Territory, Abuja. The hospital receives patients from all over Nigeria, with large clientele capacity for a host of medical conditions including stroke. This description of the study methods will be useful for clinicians and researchers in planning and implementing studies of this kind.

ETHICAL APPROVAL

This study will be conducted in strict adherence to the declaration of Helsinki (DOH) and public health,²⁵ according to which human subjects' safety should not be undermined for the purpose of conducting any form of research that involve human subjects. Ethical clearance has been obtained from the Research and Ethics Committees of Aminu Kano Teaching Hospital and National Hospital Abuja with reference numbers NHREC/21/08/2008/AKTH/EC/1615 and NHA/EC/03/2016 respectively.

REFERENCES

1. Norrving B, Puska P, Mendis S, Organization WH. Global Atlas on cardiovascular disease prevention and control. Geneva: World Health Organization in collaboration with the World Heart Federation and the World Stroke Organization; 2011. ISBN: 9789241564373.
2. Kim AS, Johnston SC. Temporal and geographic trends in the global stroke epidemic. Stroke. 2013 May 24;44(6, Supplement 1):S123–S125.
3. Langhorne P, de Villiers L, Pandian JD. Applicability of stroke-unit care to low-income and middle-income countries. The Lancet Neurology. 2012 Apr;11(4):341–348.
4. Kwok C, McIntyre A, Janzen S, Mays R, Teasell R. Oral care post stroke: A scoping review. Journal of Oral Rehabilitation. 2014 Sep 22;42(1):65–74.
5. Lopez AD, Mathers CD, Ezzati M, Jamison DT, Murray CJ. Global and regional burden of disease and risk factors, 2001: Systematic analysis of population health data. The Lancet. 2006 May;367(9524):1747–57.
6. Lemogoum D, Degaute J-P, Bovet P. Stroke prevention, treatment, and rehabilitation in Sub-Saharan Africa. American Journal of Preventive Medicine. 2005 Dec;29(5):95–101.
7. Løe H. Oral hygiene in the prevention of caries and periodontal disease. International Dental Journal. 2000 Jun;50(3):129–139.
8. Fran et al
9. Stroke foundation
10. 2011. [place unknown: publisher unknown]. National hospital Abuja; 2005 [cited 2016 Jun 6]. Available from: <http://nationalhospitalabuja.net>.

11. WHO MONICA Project Principal Invest. The world health organization monica project (monitoring trends and determinants in cardiovascular disease): A major international collaboration. *Journal of Clinical Epidemiology*. 1988;41(2):105–14.
12. Ogun SA, Ojini FI, Ogungbo B, Kolapo KO, Danesi MA. Stroke in south west Nigeria: A 10-Year review. *Stroke*. 2005 May 5;36(6):1120–2.
13. Gregson JM, Leathley M, Moore AP, Sharma AK, Smith TL, Watkins CL. Reliability of the tone assessment scale and the modified ashworth scale as clinical tools for assessing poststroke spasticity. *Archives of Physical Medicine and Rehabilitation*. 1999 Sep;80(9):1013–6.
14. Katz R. Objective quantification of spastic hypertonia: Correlation with clinical findings. *Archives of Physical Medicine and Rehabilitation*. 1992 Apr;73(4):339–47.
15. Wang C-H, Hsieh C-L, Dai M-H, Chen C-H, Lai Y-F. Inter-rater reliability and validity of the stroke rehabilitation assessment of movement (STREAM) instrument. *Journal of Rehabilitation Medicine*. 2002 Jan 1;34(1):20–4.
16. Daley K, Mayo N, Wood Dauphinee S. Reliability of scores on the Stroke Rehabilitation Assessment of Movement (STREAM) measure. *Physical Therapy*. 1999; 79(1):8-19; quiz 20-3.
17. Platz T, Pinkowski C, van Wijck F, Kim I-H, di Bella P, Johnson G. Reliability and validity of arm function assessment with standardized guidelines for the Fugl-Meyer test, action research arm test and box and block test: A multicentre study. *Clinical Rehabilitation*. 2005 Jun 1; 19 (4):404–11.
18. Van Wegen E, Nijland R, Verbunt J, van Wijk R, van Kordelaar J, Kwakkel G. A comparison of two validated tests for upper limb function after stroke: The wolf motor function test and the action research arm test. *Journal of Rehabilitation Medicine*. 2010; 42 (7):694–6.
19. Yozbatiran N, Der-Yeghiaian L, Cramer SC. A standardized approach to performing the action research arm test. *Neurorehabilitation and Neural Repair*. 2007 Apr 4;22(1):78–90.
20. Cascaes AM, Peres MA, Demarco FF, Santos I, Matijasevich A, Barros AJ. Validity of 5-year-old children's oral hygiene pattern referred by mothers. *Rev Saude publica*. 2011 Aug; 45(4):668-75.
21. Slade GD. Derivation and validation of a short-form oral health impact profile. *Community Dentistry and Oral Epidemiology*. 1997 Aug;25(4):284–90.
22. Montero J, Macedo C, Lopez-Valverde A, Bravo M. Validation of the oral health impact profile (OHIP-20sp) for Spanish edentulous patients. *Medicina Oral Patología Oral y Cirugía Bucal*. 2012:e469–e476.
23. Oliveira BH, Nadanovsky P. Psychometric properties of the Brazilian version of the oral health impact profile-short form. *Community Dentistry and Oral Epidemiology*. 2005 Aug;33(4):307–14.
24. Morse JM. Is qualitative research complete? *Qualitative Health Research*. 1996 Feb 1;6(1):3–5.
25. World medical association declaration of Helsinki. *JAMA*. 2013 Nov 27;310(20):2191.
26. Bernspang B, Asplund K, Eriksson S, Fugl-Meyer AR. Motor and perceptual impairments in acute stroke patients: Effects on self-care ability. *Stroke*. 1987 Nov 1;18(6):1081–6.