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

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Authors' contributions

IR and IUL conceived the idea for the study and developed the title. Authors RI and IUL contributed to the research design. Authors RI, IUL and KJR were principally responsible for the drafting of the manuscript. All authors contributed in deciding the choice of outcome measures of the study. Authors RI, IUL and KJR assisted in editing the final submitted manuscript. All authors have read and approved the manuscript.

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Study Protocol

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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

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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.

1. INTRODUCTION

Cardiovascular diseases contribute largely to Non-Communicable Diseases (NCDs). Approximately seventeen million deaths occur annually due to cardiovascular diseases (including stroke) worldwide [1]. 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 countries [2]. The burden of stroke is rapidly escalating, with the burden of the brunt more in poor than rich communities [3].

Annually about fifteen million people worldwide are affected by stroke, [4] and an estimated 80% of all deaths from stroke will occur in low-income and middle-income countries [5]. The high social and economic burden of stroke calls for effective strategies for prevention, treatment, and rehabilitation in SSA [6].

Oral health care is considered as one crucial aspect of self-care. Individuals who have suffered stroke may have difficulty to independently complete the needed oral health care tasks [4], 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 [4]. A previous study has identified poor oral hygiene among stroke survivors to be a cause of pneumonia, systemic infection, endocarditis and even death [4]. 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 concerns [7].

According to the stroke foundation, [8] 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. 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. Likewise, the patient's perspective is a crucial element of evidence-based practice [9].

By providing insight in to the perspectives of individuals who have firsthand experience, qualitative strand can complement quantitative strand to provide a valuable contribution to the development of services and interventions that are important to stroke survivors [10]. With this approach there will be a greater insight in to stroke survivors and their health care providers' perception regarding oral hygiene status post stroke, also their opinion regarding the oral health needs post stroke.

This study is therefore designed to investigate the relationship between upper extremity motor function and the state of oral hygiene in stroke survivors, also, to explore the perception of stroke survivors and their health care providers about oral health post stroke.

This paper describes the study protocol.

2. METHODOLOGY

2.1 Design

An explanatory sequential mixed- method design (Fig. 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.

2.2 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 Nigeria [11]. 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.

2.3 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 Organization [12] 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 3 months ago; lost at least half of their teeth; have history of poor oral health prior to the occurrence of the stroke; present mental instability or receptive aphasia, being completely unconscious, irritable or medically unstable.

2.4 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% [13] 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.

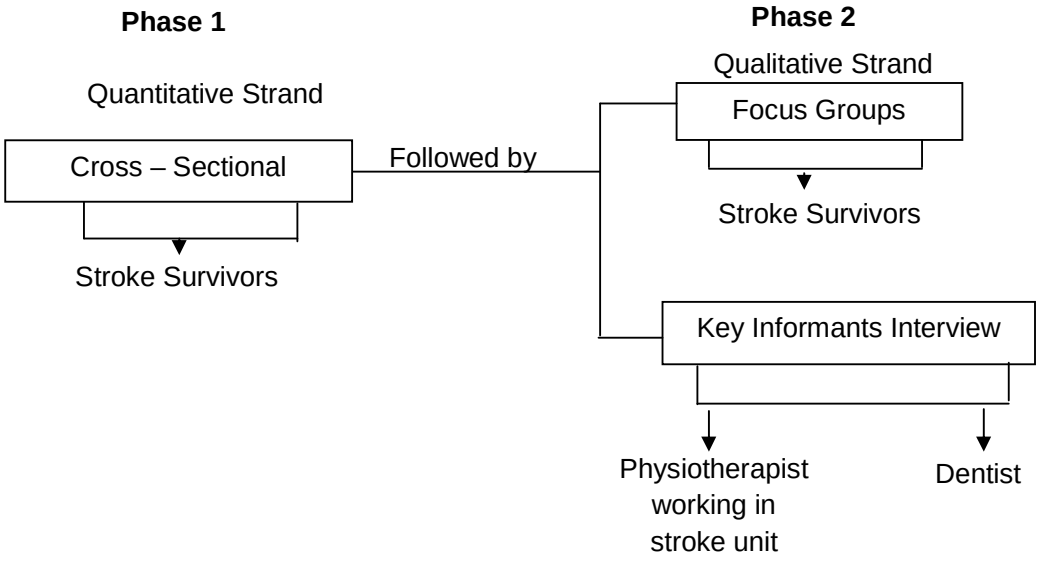

Fig. 1. Study design

Table 1. Data collection instruments

Scales	Description
Modified Ashworth Scale (MAS)	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 (kw > 0.84), in stroke population[14] 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.[15]
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 (α = 0.965), limb subscales (α= 0.979) [16] and overall STREAM scores (α = 0 .984).[17]
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 *and* 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 [18], internal consistency α = 0.985 [19] and construct validity in relation to the arm section of Fugl Meyer, ICC = 0.925 [19]. An excellent correlation was reported (r = 0.94, p<0.01) between ARAT and Arm motor score of the Fugl-meyer[20]. 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

Scales	Description
	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 assessment.[21]
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-49.[22] 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, were 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.[23],[24]

2.5 Data Collection Approaches

2.5.1 Quantitative strand (phase 1)

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

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

2.5.1.1 Socio-demographic characteristics

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

2.5.1.2 Stroke limitation constructs

The criterion rehabilitation measures (MAS, STREAM and ARAT) will be used to assess the motor function of the affected upper extremity of the participants. Upper extremity spasticity, mobility and performance are basically the variables to be measured in this construct. In this study, three major upper extremity joints; shoulder, elbow and wrist will be considered for spasticity measurement, all movement that occur in each of these three joints will be assessed for spasticity using the MAS. In each joint the highest MAS score will be recorded.

2.5.1.3 Oral hygiene constructs

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

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

2.5.2 Qualitative strand (phase 2)

2.5.2.1 Summary

Two methods of data collection will be employed in this phase; Focus Group Discussions and in-depth interviews (key informants' interview).

Focus Group Discussion of the stroke survivors and individual interviews of experienced physiotherapists working in the stroke unit and dentists will be conducted.

2.5.2.2 Focus groups

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

2.5.2.3 Individual interviews

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

2.5.3 Data management and analysis

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

2.5.3.1 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 [25]. 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.

3. RESULTS

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

4. 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.

5. CONCLUSION

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

CONSENT

As per international standard or university standard, patient's written consent has been collected and preserved by the author(s).

ETHICAL APPROVAL

This study will be conducted in strict adherence to the declaration of Helsinki (DOH) and public health, [26] 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 referen ce numbers NHREC/21/08/2008/AKTH/EC/1615 and NHA/EC/03/2016 respectively.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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