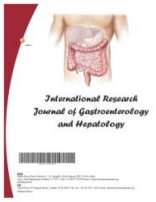

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Functional Bowel Disorders, Psychosocial Correlates and Health-related Quality of Life in a Nigerian Community: Ilisan-Remo Functional Bowel Disorders Project Protocol

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Authors' contributions

This work was carried out in collaboration among all authors. Author ACJ designed the study, wrote the initial draft of the protocol and managed literature search. Author KOA reviewed the protocol. Author OOA reviewed the protocol. Author CJE reviewed the protocol. Author OAF reviewed the protocol and made critical input to the mental health aspect. Author TOA reviewed the protocol. All authors read and approved the final manuscript.

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Study Protocol

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ABSTRACT

Introduction: Functional bowel disorders are functional gastrointestinal disorders affecting the middle or lower gastrointestinal tract. They occur worldwide and manifest with features of abdominal pain, bloating, distention, and/or bowel habit abnormalities such as diarrhea, constipation, or mixed diarrhea and constipation. Though benign, their interference with the patient's daily activities constitutes a substantial socioeconomic burden. There is paucity of data concerning the functional bowel disorders and their psychosocial correlates, apart from irritable bowel syndrome, in Nigeria. More especially, these disorders have not been studied with the Rome IV iteration in the country. This study aims at bridging the observed gaps.

Materials and Methods: The study shall be a descriptive cross-sectional community-based study. The study population shall consist of a cohort of 500 consenting adults aged 18 to 70 years who are residents of Ilisan-Remo, Ogun State, Nigeria. A composite questionnaire consisting of demographic data, medication history, the Rome IV Functional Bowel Disorder questionnaire, the Becks Anxiety, and Depression Inventories, the Pittsburgh Sleep Quality Index, the Early Trauma Inventory-Self Report, Short Form 12, version 2 Health Survey (SF-12v2) questionnaire and other relevant questions shall be used to obtain data from the participants. We shall analyze the data obtained with the IBM- Statistical Package for Social Sciences (SPSS), version 22.

Discussion: The present study would be the first study to investigate a group of FBDs in Nigerian community using the Rome IV criteria. The study would investigate the association between the FBDs and a comprehensive list of prospective risk factors which include anxiety, depression, early trauma exposure, sleep quality, abdominal obesity, cigarette smoking, alcohol consumption, coffee intake, and physical exercise in a Nigerian population. It would also evaluate the health-related quality of life in persons who suffer from the FBDs and help to create awareness of the diseases.

Conclusion: When completed, this study would provide vital information concerning the prevalence, risk factors and health-related quality of life of functional bowel disorders in a black African population.

Keywords: Functional bowel disorders; irritable bowel syndrome; functional constipation; functional diarrhea; risk factors; health-related quality of life.

1. INTRODUCTION

Functional Gastrointestinal Disorders (FGIDs) are simply defined as disorders of Brain-Gut interaction [1]. They are the most commonly diagnosed gastrointestinal diseases worldwide and include various diseases affecting different regions of the gastrointestinal tract (GIT). They include esophageal disorders, gastroduodenal disorders, bowel disorders, biliary disorders, and anorectal disorders [1]. The Rome IV iteration identifies 33 adult and 20 pediatric disorders which affect different regions of the GIT as FGIDs [2].

Functional bowel disorders (FBDs) are FGIDs with symptoms referable to the middle or lower gastrointestinal tract [1,3]. Functional bowel disorders are highly prevalent, occur worldwide and could affect all members of the society without regard for age, gender, race, creed, color or socioeconomic status [3]. They are a range of chronic gastrointestinal disorders that manifest with predominant clinical features of abdominal pain, bloating, distention, and/or bowel habit abnormalities such as diarrhea, constipation, or mixed diarrhea and constipation [3].

Chronic abdominal pain, diarrhea, constipation, bloating, and stool irregularity are common symptoms in primary care and gastroenterology practice [4]. Routine diagnostic evaluations often fail to reveal any underlying structural abnormality in about a half of persons affected by these health problems who are thus said to have FBDs [4,5].

Functional bowel disorders are largely considered benign in the medical sense because they neither shorten life expectancy nor cause organic damage [4]. They, however, interfere with the day to day activities of the patients in varying degrees. Such interference results in reduced productivity because of ill-health and avoidance of pleasurable activities such as eating out at restaurants or going on vacation [4]. The economic burden to the society is significantly raised by diagnostic tests and

treatments for which there is no indication and by work absenteeism from medical excuses [4].

The Rome iteration classifies FBDs into 5 distinct categories: irritable bowel syndrome (IBS), functional constipation (FC), functional diarrhea (FD), functional abdominal bloating/distention, and unspecified FBD. A sixth category called opioid-induced constipation (OIC) has been added to this group in the Rome IV iteration. Though OIC is distinct from the FDBs because it has a specific etiology, the symptoms produced could mimic FC [3].

Several risk factors have been associated with IBS. These include younger age, female gender, family history of FBDs, previous history of physical or sexual abuse, intestinal infection, psychological stress, anxiety, depression, dietary factors, and sleep disorders [6]. No definite psychological feature or personality has been found to be associated with constipation [7], though persons with severe constipation and normal intestinal transit could have increased psychological distress as compared to those with slow transit constipation, and depressed patients could have constipation [7,8]. A very limited number of studies have addressed the pathophysiology of FD [8]. Psychosocial factors in FD have also not received much research attention apart from the finding of accelerated colonic transit inducible by acute stress [9].

Among the six categories of FBDs IBS and FC are the most investigated, the rest are less investigated [10]. Functional bloating is often investigated in association with the two most investigated FBD (IBS and functional constipation) and usually diagnosed after the exclusion of functional dyspepsia [10], while unspecified functional bowel disorder is diagnosed by findings of bowel symptoms that are not attributable to an organic etiology and do not meet the criteria for other categories of FBDs [10]. Since functional dyspepsia, whose absence is required to diagnose functional bloating, is beyond the scope of this study, the survey will focus on IBS, FC, OIC, FD, their probable risk factors and the health-related quality of life in those affected by the disorders.

2. RATIONALE FOR THE STUDY

Few, mostly non-population based, studies have been conducted in Nigeria to evaluate the prevalence of IBS [11–19] but the other FBDs are largely uninvestigated. One of these studies, a community-based, which had a prevalence of 31.6%, was conducted with the Rome II criteria [13] while the other, a nation-wide study, conducted with the Rome III had a prevalence of 12.2% [19]. To the best of our knowledge, no study has attempted a community survey of a group of functional bowel disorders, particularly with the Rome IV criteria, in Nigeria. This study, therefore, aims to bridge the observed gaps.

3. OBJECTIVES

The main objective of the study is to determine the prevalence of four FBDs i.e. IBS, FC, OIC and FD in Ilisan-Remo, Nigeria. Secondarily, we intend to determine the associations between the disease entities and psychosocial factors such as depression, anxiety early life trauma, sleep quality, cigarette smoking etc. and evaluate the health-related quality of life of persons affected.

4. MATERIALS AND METHODS

4.1 Study Design

The study shall be a descriptive cross-sectional community-based study.

4.2 Study Population and Location

The study population shall consist of a cohort of consenting adults aged 18 to 70 years who are residents of Ilisan-Remo. Ilisan-Remo is a sub-urban community in Ogun State, Southwest Nigeria. The town is centrally located between Ibadan and Lagos. It lies on Latitude 6.8932^0 North and Longitude 3.7105^0 East. It has a population that is slightly above 10,000. Ilisan-Remo is the host community to the Babcock University and the Babcock University Teaching Hospital, Nigeria. The population is a mixture of well-educated civil servants and Babcock University workers who reside in the community, and the not-so-educated artisans, petty traders, and subsistence farmers.

4.3 Sample Size

Using the Leslie-Fischer formula [20] and 32% which is the proportion of persons with IBS found in a previous Nigerian community-based study that utilized the Rome II criteria [13], the calculated sample size required is 334. Making an adjustment to compensate for missing or incomplete data with an anticipated response rate of 90% (0.9), the minimum sample required is 382. This will be rounded up to 500 in order to increase the power of the study.

4.4 Sampling Method and Data Collection

There are 51 major streets in Ilisan-Remo township out of which 10 streets shall be randomly selected by ballot. Consenting adults aged 18-70 living in the households on each of the selected streets shall be interviewed by well-trained research assistants until the sample size has been completed. If the desired sample size could not be gotten from the 10 selected streets, more streets shall be selected until the number is reached.

4.5 Selection Criteria

Persons aged 18-70 years who consent to participate in the study shall be included. However, apparently pregnant women, persons with confirmed diabetes mellitus, persons with a recent history of abdominal surgery (three months), persons with a known history of peptic ulcer disease, persons with prolonged fever, persons with unintentional weight loss and persons with bleeding per rectum shall be excluded.

4.6 Data Collection and Instrument

A composite questionnaire consisting of demographic data, medication history, the Rome IV Functional Bowel Disorder Modular Questionnaire, the Becks Anxiety and Depression Inventories, the Pittsburgh Sleep Quality Index, the Early Trauma Inventory-Self Report, Short Form 12, version 2 Health Survey (SF-12v2) questionnaire and other relevant questions shall be used. A copy of the Bristol Stool Scale (BSS) shall be shown to each participant for easy assessment of stool form. We are unable to make the data collection instrument available because of copyright issues regarding some of the questionnaires to be used.

4.6.1 Irritable bowel syndrome assessment

Diagnosis of IBS shall be made with the Rome IV IBS criteria [2].

4.6.1.1 Diagnostic Criteria for irritable bowel syndrome*

Recurrent abdominal pain, on average, at least 1 day per week in the last 3 months, associated with 2 or more of the following criteria:

1. Related to defecation.
2. Associated with a change in frequency of stool.
3. Associated with a change in form (appearance) of stool.

*Criteria fulfilled for the last 3 months with symptom onset at least 6 months before diagnosis.

IBS is further classified into four subgroups by Rome IV: IBS-Constipation (IBS-C), IBS-Diarrhea (IBS-D), IBS-Mixed (IBS-M), IBS-Unclassified (IBS-U).

The diagnosis of IBS can be reasonably made using the Rome IBS criteria as long as the patient does not have “red-flag” symptoms like drastic weight loss, a history of organic bowel disease, a history of digestive surgery, bloody stool, and night awakening due to abdominal pain, anemia, or fever [21,22].

4.6.2 Functional constipation assessment

Diagnosis of functional constipation shall be made with the Rome IV functional constipation criteria [2].

4.6.2.1 Diagnostic Criteria for functional constipation*

1. Must include 2 or more of the following:
   a. Straining during more than one-fourth (25%) of defecations.
   b. Lumpy or hard stools (BSS 1-2) more than one-fourth (25%) of defecations.
   c. Sensation of incomplete evacuation more than one-fourth (25%) of defecations.
   d. Sensation of anorectal obstruction/ blockage more than one-fourth (25%) of defecations.
   e. Manual maneuvers to facilitate more than one fourth (25%) of defecations (e.g. digital evacuation, support of the pelvic floor).
   f. Fewer than 3 spontaneous bowel movements per week.
2. Loose stools are rarely present without the use of laxatives.
3. Insufficient criteria for irritable bowel syndrome.

*Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis.

4.6.3 Opioid induced constipation assessment

Diagnosis of opioid induced constipation shall be made with the Rome IV functional constipation criteria [2].

4.6.3.1 Diagnostic criteria for opioid induced constipation*

1. New, or worsening, symptoms of constipation when initiating, changing, or increasing opioid therapy, that must include two or more of the following:

   a) Straining during more than one-fourth (25%) of defecations.
   b) Lump or hard stools (BSS 1-2) more than one-fourth (25%) of defecations.
   c) Sensation of incomplete evacuate more than one-fourth (25%) of defecations.
   d) Sensation of anorectal obstruction/ blockade more than one-fourth (25%) of defecations.
   e) Manual maneuvers to facilitate more than one fourth (25%) of defecations (e.g. digital evacuation, support of the pelvic floor).
   f) Fewer than 3 spontaneous bowel movements per week.

2. Loose stools are rarely present without the use of laxatives

*Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis.

4.6.4 Functional diarrhea assessment

Diagnosis of functional diarrhea will be made with the Rome IV functional diarrhea criteria [2].

4.6.4.1 Diagnostic Criterion[*] for functional diarrhea

Loose or watery stools, without predominant abdominal pain or bothersome bloating, occurring in >25% of stools[†].

[*]Criterion fulfilled for the last 3 months with symptom onset at least 6 months before diagnosis.

[†]Patients meeting criteria for diarrhea-predominant IBS should be excluded

4.6.5 The Bristol Stool Scale

The Bristol stool scale (BSS) or the Bristol stool chart (BSC) is a medical aid designed to classify the form of human feces into seven categories. It was developed by Lewis and Heaton at the University of Bristol and published in 1997 [23]. There are seven (7) types of stool according to the scale. These include:

Type 1: Separate hard lumps, like nuts (hard to pass).

Type 2: Sausage-shaped, but lumpy.

Type 3: Like a sausage but with cracks on its surface.

Type 4: Like a sausage or snake, smooth and soft.

Type 5: Soft blobs with clear cut edges (passed easily).

Type 6: Fluffy pieces with ragged edges, a mushy stool.

Type 7: Watery, no solid pieces, entirely liquid.

Types 1 and 2 indicate constipation, with 3 and 4 being the ideal stools (especially the latter), as they are easy to defecate while not containing excess liquid, and 5, 6 and 7 tending towards diarrhea.

The authors concluded that the form of the stool is a useful surrogate measure of colon transit time. This conclusion has since been challenged as having limited validity [24]. The scale, however, remains a useful research tool in clinical communication and in evaluating the effectiveness of treatments for various bowel diseases [25].

4.6.6 Assessment of psychological disorders (Anxiety and Depression)

We shall assess anxiety and depression in the subjects with the Beck Anxiety Inventory (BAI) and the Beck Depression Inventory (BDI-II) respectively.

4.6.6.1 Beck's anxiety inventory

The Beck Anxiety Inventory was designed by Beck et al in 1988 as a screening tool for anxiety [26]. The instrument is a 21-item self-reported inventory with statements descriptive of anxiety symptoms subjects experienced during the past week of their lives, rated on a Likert scale of 4 points. The possible range of total scores goes from 0 to 63. It takes 5 to 10 minutes to complete the inventory. The instrument has been validated by several studies and found to be a reliable measure of anxiety symptoms in different populations [27–32].

4.6.6.2 Beck's depression inventory

The Beck Depression Inventory (BDI) was designed by Beck et al in 1961 for the

assessment of depression [33]. It is a 21-question multiple-choice self-report inventory with a score range of 0-63. It has undergone two revisions since it was created: the BDI- the original version, first published in 1961; the BDI-1A, first revision in 1978; and the BDI-II, second revision in 1996. The BDI is widely used as an assessment tool by health care professionals and researchers in a variety of settings.

4.6.7 Assessment of early trauma exposure

Exposure to early life trauma shall be assessed using the Short Form, Self-Report version of Bremner's Early Trauma Inventory (ETISR-SF) [34]. The ETISR-SF contains 27 'true' or 'false' items and has been psychologically validated to assess exposure to traumatic experiences before the age of 18. This inventory is divided into four scales measuring: general trauma (11 items), physical punishment (5 items), emotional abuse (5 items), and sexual abuse (6 items). A total score, and the four individual sub-scale scores, is generated by summing the number of positive responses.

4.6.8 Assessment of sleep quality

Sleep quality shall be assessed by the Pittsburgh Sleep Quality Index (PSQI). The PSQI is an effective instrument employed in measuring sleep quality and patterns in adults. It measures seven components to discriminate "poor" from "good" sleep quality: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medications, and daytime dysfunction over the last month [35].

4.6.9 Assessment of health-related quality of life

The health-related quality of life (HRQoL) of the participants shall be assessed by the Short Form-12, version 2 (SF-12v2). The SF-12v2 is a generic HRQoL instrument composed of two-component scores: The Physical Component Summary (PCS12) and the Mental Component Summary (MCS12) [36,37]. The PCS12 and the MCS12 measure the latent concepts of physical and mental HRQoL respectively. Each of the components is scored on a scale from 0 to 100 with a mean of 50 and a standard deviation of 10, where the higher scores represent better health. While the PCS12 focuses on participants' general overall health, limitations in mobility, work, and other physical activities as well as limitations due to pain; the MCS12 involves participants' limitations in social activity, emotional state, and level of distraction.

4.6.10 Waist circumference

The abdominal girth (in centimeter) of all the participants shall be taken with a flexible tape rule at the level of the umbilicus as a measure of abdominal obesity.

4.6.11 Physical examination and stool test

All persons who fulfill the diagnostic criteria for the bowel disorders shall be invited to the Babcock University Teaching Hospital for general physical and abdominal examination. Fresh stool samples of all participants who fulfill the diagnostic criteria for IBS and FD shall be collected for microscopy, culture and sensitivity to exclude infectious etiology. Participants with abdominal mass and/or stool positive for parasitic infestation or microbial infection shall be excluded.

4.7 Statistical Analysis

We shall analyze data with the IBM-Statistical Package for Social Sciences (SPSS), version 22. Continuous variables shall be presented as means ±SD and range. Means shall be compared with the Independent Student t-test where appropriate. Categorical variables shall be expressed as frequencies and percentages and ratios. The unadjusted odds ratios of prospective risk factors of the FBDs shall be calculated by univariate analysis where appropriate. Binary logistic regression analysis shall be used to eliminate the effect of possible confounders on the risk factors that are found to be significant during univariate analysis to get the adjusted odds ratios. Variables with odds ratio (OR) > 1 and P-value < 0.05 shall be considered significant.

4.8 Information Dissemination

The data generated shall be disseminated through presentations at scientific conferences and publications in peered reviewed journals. Participants' identifiers shall not be revealed.

4.9 Follow-up Strategy

The contact information of participants shall be obtained and kept safely for follow up purposes. Participants shall be followed up for a minimum

of 5 years. Those with positive diagnoses of the FBDs shall be evaluated at a yearly interval to observe the pattern of symptoms evolution and remission. Those without diagnoses of the FBDs shall also be evaluated yearly to determine the annual incidence of the FBDs.

5. DISCUSSION

As already stated, the FBDs are generally uninvestigated in Nigeria, except IBS which has been investigated by a few groups of researchers. Therefore, the conduct of a study with broad objectives like this is highly desirable in the Nigerian population.

We believe this study has several innovative aspects and benefits. First, it would be the first study to investigate a group of FBDs in a cohort of participants in a Nigerian community. Second, it is the first that would utilize the Rome IV criteria to investigate FBDs in a Nigerian population. Third, it is the first that would investigate the association between the FBDs and a comprehensive list of prospective risk factors which include anxiety, depression, early trauma exposure, sleep quality, abdominal obesity, cigarette smoking, alcohol consumption, coffee intake, and physical exercise in a Nigerian population. Fourth, it is the first that would evaluate the health-related quality of life in persons who suffer from the FBDs in Nigeria. Fifth, the follow-up strategy would allow us to observe the pattern of evolution and remission and the annual incidence of the disorders. Sixth, the study will help to create awareness about the disorders among the participants and afford those who may have been suffering from any them in silence the opportunity to access professional care. More importantly, it could be an impetus for other Nigerian researchers to look in the direction of functional bowel disorders.

Notwithstanding, this effort could be challenged by inadequate funding, though we hope to overcome this with prudent resource management. The fact that the study would be conducted among adults (≥18 years) has automatically excluded children and adolescents from participating. Therefore, the results that would be obtained may not be a complete representation of the FBDs in the community.

6. CONCLUSION

When completed, this study would provide vital information concerning the prevalence, risk factors and health-related quality of life of the selected functional bowel disorders in a black African population. The generated data would also serve as a reliable reference for related future works because the study would be conducted in the community.

CONSENT AND ETHICAL APPROVAL

Ethical clearance has been obtained from the Ethics Review Committee of the Babcock University, Ilisan-Remo (BUHREC044/19). Written informed consent shall be obtained from all participants. The data generated shall be disseminated through presentations at scientific conferences and publications in peered reviewed journals. Participants' identifiers shall not be revealed.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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