Title: Estimating the prevalence, quality of life, economic and societal impact of arthritis in Tanzania: Protocol for a mixed methods study.

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Abstract

Introduction

Musculoskeletal (MSK) disorders are one of the major causes of disability globally. A 2010 Global Burden of Disease study reported that MSK diseases account for 20% of all Years Lived with Disability (YLDs) in Low- and Middle-Income countries. This study will use mixed methods to generate new findings on the prevalence, quality of life, economic and societal impact of musculoskeletal disorders (including arthritis) in the Hai district in Tanzania.

Methods and analysis

In this mixed-methods study funded by the UK's National Institute for Health Research (NIHR) Global Health Research Units and Groups (Award no: 17/63/35) we will conduct quantitative, community-based (urban, peri - urban and rural) and hospital based prospective surveys, supported by rapid ethnographic assessments (REAs), in-depth interviews, focus group discussions (FGDs) and clinical diagnostic screening to estimate the prevalence, economic and societal impact of arthritis. A retrospective medical records baseline review at the Kilimanjaro Christian Medical Centre (KCMC) will also be conducted to assess prevailing documentation and management of arthritis.

Ethics and dissemination

Ethical approval has been obtained through Kilimanjaro Christian Medical University College (KCMUCo) Research Ethics and Review committee (CRERC) in Moshi, National Health Research Ethics Committee (NatHREC) of the National Institute for Medical research (NIMR) in Tanzania and the Medical Veterinary and Life Sciences (MVLS) Ethics committee at the University of Glasgow, UK (MVLS ethics project number:20018010). We will disseminate the findings in clinical, epidemiological, and economic peer reviewed journals. Other dissemination modalities include professional conferences, short reports, community leaflets, policy briefs and dissemination events to communities and various stakeholders including the Ministry of health in Tanzania.

Keywords: musculoskeletal disorders, quality of life, economics, prevalence, Tanzania

Introduction

In relation to their huge disability burden, the diagnosis, treatment and management of musculoskeletal (MSK) disorders have received inadequate attention worldwide.(1,2) This is particularly true for the global south, especially East Africa where infectious diseases such as malaria, tuberculosis and HIV have traditionally consumed much of the health care resources.(3) With strategies to control many communicable diseases now being identified and implemented, attention is turning to the ever-growing health and economic challenges associated with non-communicable diseases (NCDs). Among NCDs, MSK disorders are not typically prioritised for a number of reasons including the notion that they carry a low mortality compared to the diseases mentioned in the Sustainable Development Goals.(1,2) However, MSK disorders are the largest contributor to Years Lived with Disability (YLD) worldwide, amounting to 149 million YLD.(4) Indirect costs such as lost work productivity caused by MSK disorders and arthritis are known to be greater than their direct health care costs.(5–9). This is particularly pertinent to populations already experiencing significant poverty such as those in low resource settings such as Tanzania. The prevalence of MSK and arthritis is hypothesised to be high in Tanzania and this is likely to have even greater impacts on poverty because of inability to work (indirect cost impacts) and wider household/agricultural productivity impacts as well as inability to fulfil community roles. Such high indirect costs and compounding impacts upon quality of life and depression are well documented in developing countries but little evidence exists for Tanzania. The health and economic burdens of MSK disorders are almost entirely under-reported in sub-Saharan Africa (SSA), including East Africa.

The existing evidence on the prevalence of MSK and arthritis is sparse with highly inconsistent estimates for SSA. A review revealed the prevalence of joint pain between 20% and 33% among people in lower- and middle-income countries.(10,11) MSK studies in SSA have typically focussed on Rheumatoid Arthritis (RA) which carries a high morbidity and considerable mortality in SSA. (12) A systematic review of the prevalence of arthritis in Africa (13), identified the paucity of recent clinical data from SSA, outside South Africa. Over a period of almost forty years, twenty-seven studies assessed the prevalence of arthritis in Africa with only one of these carried out in SSA and this was focussed on HIV related disease. (13,14) In Tanzania, the morbidity associated with arthritis was found to be significant in a hospital-based study with over 60% of patients requiring assistance with mobility and very few managing to access specialist care at a distant centre. (15) Populations in low resource settings clearly carry the burden of MSK disorders but have fewer resources , including adequate service provision, to diagnose and treat such conditions. A study that explores both community and hospital prevalence and case mix, quantifies the economic and quality of life impacts and illuminates personal experiences and existing management strategies has the potential to inform future policy and health care practice for the largely undiagnosed population who suffer silently from MSK disorders.

Early and intensive treatment of MSK disorders including inflammatory arthritis has been demonstrated to improve functional outcomes among patients (16). Reliable local data on the burden of MSK disorders therefore has the potential to strengthen advocacy in resource allocation for early intervention leading to decreased disability and higher quality of life. There has been increasing recognition of the need for action in SSA with input from the International League Against Rheumatism (ILAR) (17) and the African League against Rheumatism (AFLAR)(3). However, in Tanzania there are presently no data on the prevalence of arthritis, nor on how people experience and manage the disease or the impact it has on income, productivity, health care expenditure and quality of life. The need to assess community prevalence in tandem with a hospital-based survey is paramount to understanding the prevailing burden of MSK disorders in general and particularly arthritis. Such insight will inform requirements for local capacity building in MSK.

Methods and Analysis

Study settings

This study is being conducted in the Kilimanjaro region of Tanzania, commencing April 2018. The regional population is more than 1,600,000 individuals of whom about one third live in urban areas(4). The main ethnic group is the Chagga who are distributed in seven districts. These studies are being conducted in two of these districts, Moshi urban and Hai district. The Hai district was selected because it is an established site for demographic surveillance in Tanzania(18). The Hai district which is in the Kilimanjaro highlands (approximately 1900 metres above sea level) of Kilimanjaro is mainly made up of subsistence farms but also cash crops such as coffee. In contrast, Moshi urban is in the Kilimanjaro lowlands (approximately

900 metres above sea level) with temperatures between 37 degrees centigrades and 24 degrees centigrades.(19) Moshi urban was selected by convenience of location of an urban population. The lowest organisational unit at a Tanzanian street or village level is the Ten cell leader also known as a Balozi.(20) Several 10-cell leaders comprise a village which is the lowest administrative structure in the rural setting. Several villages then make up a ward followed by a district and then a region. In the urban setting, streets are in place of villages.

Objectives and Research Questions

This research study has the following objectives:

1. To estimate the prevalence of the main forms of MSK in hospital and community settings in the Hai district in Tanzania
2. To estimate the frequency of comorbid NCDs, especially with reference to those associated with arthritis and its treatment, in the community and a hospital setting in the Hai district in Tanzania
3. To assess how arthritis is understood by community members, health care professionals and patients in the Hai district in Tanzania
4. To describe the experiences of living with joint pain and arthritis in the Hai district in Tanzania
5. To describe the management of arthritis in a Tanzanian clinical setting
6. To adopt and pilot instruments to measure arthritis quality of life (QOL), health seeking behaviour & resource utilisation in community and hospital settings in the Hai district in Tanzania

Based on these objectives, this study has four key research questions:

1)What is the lived experience of joint pain and arthritis in Tanzania?

2) What instruments are best suited to measuring & valuing quality of life and resource use

3) What is the extent and nature of joint pain and arthritis in clinical settings in Tanzania?

4) What is the prevalence, health, economic and societal burden of the main forms of arthritis in Tanzania?

5) in Tanzania and can they be administered within a household survey?

Qualitative methods

Qualitative research will be conducted in two phases to address research questions 1 and 2. First, rapid ethnographic assessments(21) (REA) within pre-survey pilot sub samples will identify how people talk about and classify joint pain. Terminologies used will inform subsequent studies. Methods in the REA include 60 short interviews with community leaders, traditional healers, community members, and pharmacists. The research team will write detailed field notes and, with written consent, take photographs to develop 'thick descriptions' of the phenomena in each community. Based on these data a preliminary scheme of classification of how joint pain is understood, explained and responded to will be developed and tested through a series of focus groups with community members and semi-structured interviews with community leaders, conducted within the same communities as the REA. The focus groups will use visual representations of the body and seasonality to stimulate discussion about joint pain, and thus, to collect confirmatory and supplementary data relating to situated classifications of joint pain, to improve the scheme of classification; to document how and when joint pain interrupts daily routines, and the impact this has on the lives of informants; to identify actual and desired support-seeking strategies that those with joint pain pursue or would like to pursue, in both 'traditional' and biomedical domains; and to explore how clinical categories relating to arthritis are understood, used and acted on. The results of this phase of the qualitative research, particularly in terms identifying the words and phrases used to describe joint pain, will be used to adapt survey instruments in the quantitative component described below. Secondly, semi-structured interviews will be conducted with members of the census cohort who have reported symptoms of arthritis. They will be sampled purposely to include people of different gender and age groups. Interviews will explore situated accounts of living with arthritis symptoms, including:

i) the multiple impacts symptoms have on individuals and the livelihood of their household;

ii) the 'illness work'(22) that interviewees do to manage both symptoms and their impacts;

iii) the treatment seeking behaviour and management practices enacted by individuals, including the obstacles and challenges faced in accessing preferred treatments.

The impact of disease and the work needed to manage its effects is often understood exclusively through economic metrics; this research seeks to uncover a more holistic understanding of what it means to live with these conditions by taking seriously the emotional and everyday experiences of individuals. A range of visual methodologies will compliment semi-structured interviews, for example, the co-creation of diagrams detailing support and care in order to explore patients' social networks.(23) The co-creation methods used in these interviews will be mindful of potential enacted disclosures of literacy levels (e.g. how a pen is held), with the interviewee being asked if they would like to write/draw on the page themselves, or if they would prefer the interviewer to do this. The qualitative research will be attuned to the plurality of knowledge and experience that are often gendered, situated and livelihood dependent. Following anthropological approaches to public health, this work aims to unpack these nuanced experiences foregrounding understandings of lived experience to ensure any future interventions are appropriate to the targeted population(24).

Community-based cross-sectional survey

A community-based cross-sectional survey will be used to estimate the prevalence, economic and societal impact of arthritis in the community setting using clinical screening tools, economic and quality of life questionnaires. The community survey will comprise a representative sample of all residents (aged over 5 years old) living in Tanzania's Hai district in the Kilimanjaro region, and one street in the Moshi urban setting.

Participant selection:

Based on sample-size calculations, the study will recruit 1050 households (approximately 5701 individuals) for this cross-sectional survey, to achieve a confidence level of 95% and assuming a 15% prevalence of MSK (as estimated in the pilot study). Two-stage cluster sampling with replacement and probability proportional to the size of the village population will be used. (25) In the first stage villages will be selected from a sampling frame, and one village can be selected more than one time with the probability of selection proportional to the size of the village. In the second stage, households will be selected with random probability. The selection of households in the second stage benefits from the existing organisation of Tanzania households within Balozi, as the Balozi 'informal' infrastructure will be used to enumerate the households and to inform the households in the villages about the aims of the survey. In addition, in the Moshi urban setting one street is selected using convenience sampling. All eligible members of selected households identified in the community setting will be invited to participate in the study and asked to provide written informed consent as described in the consent section below.

Data collection:

A three-stage screening process for all participants will be followed (See Table 1: Summary of community-based research). In the first stage, all participants will be assessed using a version of the Gait Arms Legs Spine (GALS) screening test adapted for the local context and translated for delivery in Swahili. (26) An adapted version of the paediatric version (pGALS) will be delivered in Swahili for those aged 5-17 years (27) who declare locomotor limitations or symptoms. The pGALS has previously been translated into Swahili, among other languages, and shown to be practical and acceptable in children in Malawi. (28) In addition, All participants will be administered a demographic questionnaire, a short health questionnaire, and a short health-economics questionnaire (only participants >11 years). Furthermore, adult participants (18+ years) will be administered the WHO Disability Assessment Questionnaire (WHO DAS) , and the EQ-5D questionnaire(29,30), whereas minors under 18 will be administered the CHU 9D questionnaire (31). Individuals who test negative in the GALS examination will be assessed whether they are of the same sex and similar age range as already-identified REMS+ participants and, if so, will be included as controls. GALS- individuals who are not included as controls during their first visit will be asked for assent to be re-visited in case of further questions and will be revisited in case they are an appropriate control for a REMS+ case.

The second stage will be applied to GALS+ individuals as well as sex and age matched controls for REMS+ individuals and will include the modified Health Assessment Questionnaire (HAQ), and the Global Health questionnaire. GALS+ individuals (but not controls) will be administered REMS and the 66/68 swollen/tender joint count + Joint Pain Visual Analog Scale (VAS). In the third stage, all REMS+ individuals and controls will be administered the long health-economic questionnaire (only participants >11 years), be asked additional questions about their health including the presence of additional non-communicable diseases, and have their height, weight and blood pressure measured. REMS+ individuals (but not controls) will have their blood taken for laboratory analysis. In addition, ultrasound imaging will be taken from all affected joints (see Laboratory and radiological data collection section) and additional details about the participants' MSK disorders will be recorded.

Ethics considerations:

Ethical approval has been obtained through Kilimanjaro Christian Medical University College (KCMUCo) Research Ethics and Review committee (CRERC) in Moshi, National Health Research Ethics Committee (NatHREC) of the National Institute for Medical research (NIMR) in Tanzania and the Medical Veterinary and Life Sciences (MVLS) ethics committee at the University of Glasgow, UK (MVLS ethics project number:20018010).

All participants will receive an oral explanation of the survey and be given a participant information sheet and adequate time to read and ask questions. Contact information for the study coordinators and principal investigators will be provided. For patients unable to speak Swahili or English, interpretation will be provided, through family members or staff, in their tribal language. Written informed consent will be obtained for all adult participants and guardians of minor participants. Oral assent will be obtained in addition to guardian consent from all participants aged 12-17 years (more details in consenting section below).

All medical examinations, sample collection, and medical imaging will be performed by medically trained staff (nurses and medical doctors). All staff members involved in administering questionnaires and\or examinations will receive intensive training in study procedures and interview administration. Appropriate PPE will be provided to staff and participants where applicable and appropriate hygiene measures will be observed by all staff.

All community and hospital surveys will also include health economic questions on employment, income, assets and productivity, health care resource utilisation and quality of life. All data will be fully anonymised and no identifiable information will be recorded during data collection. Written informed consent information will be retained by the Kilimanjaro Clinical Research Institute in Tanzania for the appropriate duration.

Table 1: Summary of community-based research

Community survey:	
Setting	Randomly selected villages in HAI district & Majengo community in Moshi urban
Participants	Members of selected households (general population)
Research methods	Questionnaire surveys Physical examinations Medical imaging & blood testing
Instruments: (tiered according to GALS results) *denotes instruments applied to participants below 18 years of age	**Tier 1: General (all participants):** GALS (Swahili version) pGALS (Swahili version)* WHO DAS (Swahili version) EQ5D (Swahili version) Demographic questionnaire Short health questionnaire Short health economics questionnaire CHU 9D (Swahili version)* **Tier 2: GALS^{+} participants:** HAQ (Swahili version) Global Health + modified Joint Pain Visual Analog scale (Swahili version) REMS pREMS* 66/68 swollen/tender joint count* **Tier 3: REMS^{+}/pREMS^{+} participants:** Blood testing Ultrasound Long health economic questionnaireAdditional health questions Further medical examinations (height, weight, blood pressure, details on identified MSK disorders) The Tier 2 and 3 tools (excluding medical imaging, bloods and further medical exams) will also be administered the GALS- control sample from Tier1 who are age and sex-matched to REMS^{+}/66/68 joint count^{+} participants in Tier3
Community-based qualitative research	
Setting:	Randomly selected villages in HAI district
Participants:	Members of selected households (general population)
Research methods:	Focus groups (GALS^{+} community members) (Appendix 18) Semi structured interviews (GALS^{+} community members) Visualisation methods Co-creation methods

*A copy of all tools compiled into a single survey document can be requested from the authors.

Prospective Hospital-based patient survey

The aim of the prospective patient survey is to estimate the burden of musculoskeletal disorders including arthritis and other associated conditions at KCMC. In addition, the prospective study will help identify patients for selection for the qualitative component of the study on the impact of arthritis. A pilot study of patients presenting with joint pain at KCMC revealed a joint pain prevalence among hospital patients between 7% and 13% and demonstrated that trained personnel could screen around 12-13 patients per weekday. Using a prevalence rate of 7-13% and an expected number of 60-65 patients that can be screened each week, a sample size of 260 patients is expected to be screened per month among which 18-36 patients are expected to have joint pain. Data will be gathered on both outpatients and patients admitted to the medical, and paediatric wards at KCMC. Immediately following initial clinical triage in the outpatients' department, a trained research assistant will use a checklist to screen consenting patients to confirm presence of joint pain and history of trauma (to exclude joint pain with a traumatic history). Eligible patients will then be directed to a study nurse/doctor (at an 'arthritis desk' which will be set up) for formal consent and data collection according to the tiered approach outlined in Table 2 (Summary of the Hospital research). For inpatients, all admissions during the study period will be screened and exclusion criteria applied (e.g excluding patients who are unable to participate due to severity of illness), prospective study participants would then be approached for consent and data collection would proceed likewise according to the tiered approach.

Table 2: Summary of the Hospital research

Medical records audit	
Setting:	KCMC hospital
Participants:	Patients (adult) at KCMC (records only)
Research methods:	Retrospective patient records audit
Instrument:	Retrospective hospital survey tool (Appendix 3)
Prospective study:	
Setting:	KCMC hospital
Participants:	Patients admitted to the medical and paediatric ward at KCM hospital
	Patients attending outpatient and orthopaedic clinics at KCMC
Research methods:	Questionnaire survey Physical examinations
Instruments:	**Tier 1: General (all participants):**
(tiered according to GALS)	GALS (Swahili version)
* denotes instruments applied to participants below 18 years of age	pGALS (Swahili version)* WHO DAS (Swahili version) EQ5D (Swahili version)

	Long Health Economics* CHU 9D (Swahili version)* (A copy of these tools compiled into a single survey document can be requested from the authors.) **Tier 2:pGALS/GALS$^+$ participants:** HAQ (Swahili version)* REMS pREMS* 66/68 swollen/tender joint count* **Tier 3: REMS$^+$/pREMS$^+$ participants:** Blood testing Ultrasound
Hospital-based qualitative research:	
Setting:	KCMC hospital
Participants:	Outpatients and patients admitted to the medical and paediatric wards at KCMC hospital Health care providers at KCMC hospital Health care providers at Mawenzi regional hospital Health care providers at Hai district hospital
Research methods:	Focus group discussions and interviews (patients) Focus group discussions and interviews (health care providers)

*A copy of all tools compiled into a single survey document can be requested from the authors.

Researchers will firstly provide eligible patients with a Participant Information Sheet (PIS), explain the study orally and invite the patient to participate in the study. Written informed consent will be asked of all those willing to participate in the study as described in the ‘consent’ section below. In addition to the standard clinical questions, participants will also be asked locally relevant questions. For example, for the standard GALS questions, further questions such as 'can you squat' and 'can you put a basket on your head' will be asked to assess lower and upper limb function, respectively. The relevance of these questions will be explored by Tanzanian clinicians. A picture of a manikin has been added for indicating the site(s) of any pain and an additional question on previous fractures to the standard GALS screening questions (see below) in the tiered approach. Similar questions will be used in the community survey to screen and identify patients as shown in level 1 screening approach.

Both the prospective hospital survey and the community survey will also collect data on other NCDs commonly found in association with inflammatory rheumatic musculoskeletal disorders (RMDs), as these comorbidities often contribute negatively to the outcomes and impact of RMDs. Specifically, data on the presence of cardiovascular disease (CVD), hypertension, diabetes mellitus and chronic kidney disease (CKD) will be collected for all patients included in the surveys. These data will be linked to the presence of MSK disorder as gout and RA are associated with increased risks of CVD, hypertension and CKD. In addition, the treatment histories received specifically with regards to steroids and Non-Steroidal Anti-inflammatory Drugs (NSAIDS) will be recorded where relevant as these agents can be related to the later development of diabetes, hypertension and CKD. These data will be obtained by extraction from the clinical records and augmented by patient reporting. Study data will be recorded using a unique participant identification number (PIN) provided for each participant, making the information pseudonymous. The signs and symptoms of each participant will be recorded using a computer tablet-based questionnaire and employing a manikin to facilitate identification of pain location utilising Open Data Kit (ODK) software.(32)

The results from the hospital-based survey will be compared to existing data using identical techniques/instruments to a UK-based inpatient population.(33) Available data from the paediatric sample (participants aged 5-17) will also be compared with data that already exist from Malawi.(28)

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Laboratory and radiological data collection

Following completion of the screening and examinations within both the community and hospital data capture, adult patients with evidence of synovitis or joint swelling will have 20 ml blood taken for later analysis of acute phase reactants (ESR, CRP) and autoantibodies (RF, CCP, antinuclear antibodies, other antibodies as relevant). Patients below 18 years of age will likewise have a maximum of 20 ml of blood taken, but not exceeding 3 ml per kg. Ultrasound will also be performed on all patients with swollen joints and results will be stored securely with the patients' medical records according to this study's data management plan. Patients with suspected arthritis will be referred to KCMC Rheumatology clinic for clinical management, which may involve x-ray of hands and other affected joints. The cost of x-rays at KCMC will be covered by the project. All patients with articular abnormalities will also undergo ultrasound examination done by a radiologist, research assistant or physician who have been trained specifically to undertake joint ultrasound examination. A portable ultrasound machine (Phillips Lumify L12-4 Linear Array) has been procured for this purpose. Local protocols for clinical decision making informed by these additional diagnostics will be developed by local physicians and paediatricians involved in this study, in consultation with the rheumatologists in Glasgow/Newcastle who are part of the study team, to ensure consistency in clinical process, decision making and sign posting for onwards management.

Retrospective audit

A retrospective audit of all adults aged 18 years or above of hospital medical records for signs & symptoms related to joint pain and arthritis-related diagnoses and relevant comorbidities will be undertaken. The audit will establish a retrospective frequency of joint pain among patients admitted to the medical wards between 1st January, 2017 and 31st December, 2019. These reviews will be conducted by trained project personnel and the extracted data will include no personal identifying information. All patients' records are stored within the medical record department at KCMC. Trained project personnel will approach a dedicated person at the department to identify and pull out and register all hardcopy and softcopy medical department patients' admission records for the years 2017 -2019 with exclusion of those below 18 years. Documentation will be undertaken to show retrieved files, included files, excluded and reasons for exclusion or missing admission records. Information will be captured and recorded onto a standardised questionnaire within the ODK platform, including a patient's unique number, age, gender, district of residence, level of education, occupation, religion, tribe, main complains, signs and symptoms, diagnosis, investigations done, treatment, duration of hospital stay and number of admissions per year. Outcomes of admission such as death, referral to a higher facility and discharge home will also be collected.

The diagnosis captured will be the final diagnosis at the time of discharge, death or referral. Patients' re-admissions within the years 2017-2019 will be documented as separate individual admissions but marked and the patient's unique number will be similar for all years that the individual has been admitted. This is to allow documentation of trends and characteristics of admissions among specific individuals over the years.

Data obtained from this retrospective survey will be compared with community and prospective survey data. This will allow researchers of this study to explore and characterize the hospitals past and present burden of NCD disease while projecting the future situation regarding most NCDs associated with hospital admissions. All information gathered will be provided to the Tanzania hospital management, community and health policy makers via our dissemination activities including a policy brief.

Consenting

In all methods described, apart from the retrospective survey, consent will be sought for the collection of data collected on individuals' joint pain, co-morbidities related health, economic, and quality of life. Children aged 5-17 attending as inpatients will be consented via their parents/guardians, who will be provided with a PIS and sign informed consent for their children to participate. In addition to parental consent, children aged 12-17 will be asked to assent to their participation. For individuals who do not wish to participate, researchers will note their estimated age and gender to assess whether the data is subject to a participation bias. The study will not collect any other data from non-consenting individuals, and participants will not be approached again.

Data storage and security

The database will be hosted on a web-based application designed to allow researchers to upload, view and manage data. An Open Data Kit (ODK) platform(32) will be deployed for this purpose. Community and hospital survey data will be collected on ODK-programmed tablets and uploaded via secure connection to servers at KCRI. The ODK platform will be used to produce a study-specific application and shall provide interoperability functions, such as exporting data to excel spreadsheet and other statistical packages. This database will be developed and approved by the Data Management team for the study before utilisation. The data will be stored on 3 servers: primary, mirror and backup. The primary server will be used to process incoming ODK, before being backed up on mirror and backup servers. All servers are behind firewalls and locked in secure cabinets. All quantitative data will be initially stored within KCRI servers in the ODK platform. On completion of the study, or as part of routine data monitoring, the data will be extracted from ODK for analysis using statistical packages such as STATA, SPSS, R or SAS. All content analysis data will be stored as Excel spreadsheet files and transcripts stored as Microsoft Word files. Final versions of all datasets and documents will also be exported to, and made available, as ASCII and/or CSV data files, with accompanying command/syntax files, so future users will still be able to access the data.

The audio data collected during qualitative data collection will be saved separately with no participant identification information. Each data file will be catalogued in a single database, with accompanying metadata (e.g., filename, author, abstract, producer, geographic coverage, temporal period of collection, response rate, etc.) using Data Documentation (DDI) Initiative standards.

Analysis of qualitative data

REA data will be analysed using a constant-comparison method (34) to build up a preliminary classificatory scheme of the different kinds of joint pain reported in the community. Observation and documentary evidence will be used to situate the scheme. Interview data will be analysed using thematic analysis to identify the major ways in which joint pain is experienced and managed, including sources of support and help.

Statistical Analysis

Data from the community and hospital survey will be analysed using mixed-effect multivariable logistic and linear regression models with random effects for village, household, and observer to describe the prevalence and associated factors for MSK disorder among participants. Stepwise selection, likelihood ratio test, and parsimony will be used for model refinement and optimisation.

Health Economic Analysis

All health and social care resource use identified and measured in the health economic components of the surveys will be valued using available local/regional unit costs. Estimates of productivity loss (absenteeism and presenteeism) will be generated by attaching proxy values (e.g. average wage, by type of occupation, age and gender) to measured time off work, using the human capital approach. Preference based quality of life values from the prevailing Ugandan value set for the EQ-5D and CHU-9D will be attached to EQ 5D responses for all adults/children respectively. An econometric model based on the statistical relationships between quality of life and healthcare resource utilisation and socioeconomic characteristics will be built using standard regression analysis, accounting for clustering (i.e. by household/village) as well as specificities of health economics quality of life and cost data (non-normal, skewed distribution). The impact of MSK on catastrophic expenditures will be explored using principle components analysis, as well as calculating wealth asset scores. Results will be incorporated into a risk-based prediction algorithm to identify individuals and households at increased risk of poorer outcomes. Regression models will be run for predicting income/ asset levels and or Health related quality of life. The impact on the average utilisation of health services will be identified and differential effects with socioeconomic characteristics tested.

Dissemination and Implications of expected results

We will disseminate the findings in manuscripts in clinical, epidemiological, and economic peer reviewed journals. Other dissemination modalities include professional conferences, short reports, community leaflets, policy briefs and dissemination events to communities and various stakeholders including the Ministry of health in Tanzania. The results from this study will be used to guide clinical health practice, intervention design, service provision, socio cultural practices and health promotion and awareness activities both at KCMC institutional level, Kilimanjaro region and at national level. This study will highlight the prevalence of rheumatological conditions and the scope of their economic and societal impact. This research will guide Tanzania and wider SSA strategy and policy making process towards increased focus and attention to neglected rheumatological diseases. This study will act as a baseline study to be used as reference by future studies, interventions, and scientific ventures on the topic nationally and internationally.

Author Contributions

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