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STUDY PROTOCOL

Feasibility of Virtual Simulation-Based Diabetes Foot Care Education in Patients with Diabetes in Ethiopia: Protocol for a Randomized Controlled Trial

Fisseha Zewdu Amdie[1,2], Marian Luctkar-Flude[2], Erna Snelgrove-Clarke[2], Monakshi Sawhney[2], Shitaye Alemu[3], Kevin Woo[2]

[1]School of Nursing, University of Gondar, Gondar, Ethiopia; [2]School of Nursing, Queen's University, Kingston, Ontario, Canada; [3]Department of Internal Medicine, University of Gondar, Gondar, Ethiopia

Correspondence: Fisseha Zewdu Amdie, Email fmzewdu@gmail.com

Introduction: Diabetes mellitus is a rapidly growing global public health problem; the number of adults with diabetes is expected to increase from 424.9 million in 2017 to 628.6 million in 2045. Approximately 80% of diabetic patients live in low- and middle-income countries where access to care may be limited. For example, in Ethiopia, diabetes care is often rudimentary, and formal, structured diabetes education is almost non-existent. One potential solution to the lack of diabetes management education for patients could be virtual simulation-based diabetes education incorporating the contextual realities of patients in Ethiopia. Despite its great potential to improve glycemic control, delay diabetes-related complications and reduce mortality associated with diabetes, the feasibility of virtual simulation-based diabetes self-management education has not been studied in low- and middle-income settings.

Objective: The purpose of the current study is to evaluate the feasibility of a virtual simulation-based Diabetes Foot Care Education (DFCE) program among adult patients with diabetes in Ethiopia.

Methods: A randomized controlled feasibility study including participants from University of Gondar Referral Hospital (UoGRH) will be conducted. A sample of 40 participants will be recruited, of which 20 participants will receive the virtual simulation-based education program, and the other 20 participants will continue with their usual diabetes care. After the education program, a questionnaire and structured interview will be used to explore the feasibility (acceptability, practicality) and the potential impact of virtual simulation-based DFCE intervention in patients with diabetes. Data will be analyzed using SPSS version 25 using descriptive statistics, independent t-tests, paired sample *t*-test, and factorial ANOVA at significance levels of less than 0.05.

Discussion: Our study seeks to understand the perceived usefullness and usability of virtual simulation-based diabetes foot care education on behavioural (diabetes foot-care knowledge, foot self-care practices, and foot self-care efficacy). Furthermore, the study will provide insight to assist in the development of technologically assisted and contextually designed DFCE programs.

Trial Registration Number: NCT04841291 (ClinicalTrials.gov Identifier).

Keywords: diabetes mellitus, feasibility, acceptability, practicability, foot care, Ethiopia

Introduction

Diabetes is a growing health concern throughout the world; the number of adults with diabetes is expected to increase from 424.9 million in 2017 to 700 million in 2045.[1] Global healthcare expenditures related to diabetes are estimated to reach 850 billion US dollars per year by 2025.[2] Globally, approximately 80% of patients with diabetes live in low and middle-income countries and, among those, one-third (153 million) live in rural areas with minimal access to medical services.[2]

Ethiopia is the second-most populous country in Africa and diabetes is a significant public health problem with age-adjusted (20–79) prevalence of 7.2%.[3] The high prevalence coupled with poor accessibility of diabetes management and

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education programs makes the burden of diabetes and diabetes management a critically important issue in Ethiopia.[4] In order to address this need, innovative, patient-centered strategies are urgently required.[5]

One important strategy is to provide comprehensive patient education specifically directed at the needs of people with diabetes. The primary goals of diabetes education is to enhance patients' knowledge and skills, enable patients to identify the priorities of self-management, and to improve problem–solving and coping skills related to managing their health conditions.[6] Diabetes self-management education (DSME) is one such patient-centered strategy which has been adopted in other settings. DSME is broadly defined as the process of facilitating knowledge, skills, and abilities necessary for people with diabetes to perform self-care.[7] DSME is emerging as a central part of diabetes management and care[7] and is included as the standard of care in national and international guidelines.[8]

These guidelines include diabetes education and self-management strategies in particular Diabetes Foot Care Education (DFCE) strategies as essential components of diabetes care. Especially, the rising prevalence of diabetes-related complications including diabetic foot ulcers requires an integrated and continuous patient education programs.[9–11] However, studies demonstrate that the self-management knowledge and skills of adult patients with diabetes is inadequate and it is a major barrier to adequate management of diabetes[12,13] and this is particularly true in Ethiopia. A study conducted by Mariye et al in Tigray, Ethiopia reported nearly 63% of study participants had poor diabetes self-care practices associated with a lack of knowledge and limited access to diabetes education.[14]

At the University of Gondar Referral Hospital (UoGRF) in Northeast Ethiopia, over half (52%) of the patients who attended a diabetes specialty care clinic were identified as having poor self-care practices.[15] In a similar study in the Northern part of Ethiopia, 44% of participants did not know about diabetes foot care while 47% had poor foot care practices.[16] The poor self-care practices was associated with a lack of availability of diabetes education and was demonstrated among patients who, as a group, had low knowledge levels on critical topics for diabetes self-care such as blood glucose monitoring, foot care, and the role of physical activity in managing diabetes.[15,16] The low level of knowledge and self-care practices has been attributed to the absence of a structured diabetes education program in Ethiopia.[17–19]

Inaccessible diabetes education and a lack of clinicians with specialized training and expertise in diabetes education contribute to poor diabetes management and diabetes-associated complications in Ethiopia. A recent study in Dessie, Ethiopia, reported that 70% of people with Type 2 diabetes have been affected by one or more diabetes-related complications.[20] The most common diabetes-associated complications in Ethiopia include neuropathy (35%), retinopathy (25%), and kidney disease (24%).[21] Diabetes-related amputation is also high (47%) among patients with diabetes at Tikur Anbessa Hospital, Ethiopia.[22] This is mainly due to inaccessible diabetes foot care education and lack of direction in Ethiopian guidelines for diabetes experts to provide education regarding foot care.

Unlike Western countries like Canada, in Ethiopia, there are no certified diabetes educators. Clinicians involved in diabetes education include medical interns, nurses, and Health Officers who may have varying levels of training and experience on providing education to patients with diabetes even at specialized diabetes clinics.[23] Medical interns serve in general practice roles after graduating from medical School as part of the medical school financing scheme through the Ministry of Health and may have limited exposure to, or interest in, care of the diabetic patient.[24] While nurses do participate in the education and coaching of diabetic patients, specialization in diabetes care is uncommon in Ethiopia and nurses have competing priorities in the management of patient flow and multiple patient care activities. In addition, Health Officers are trained to provide primary care and follow-up on patient concerns, particularly in the rural areas of Ethiopia, but do not obtain the preparation to provide comprehensive diabetes education and self-management coaching.[25]

Another barrier to diabetes education in Ethiopia is a lack of time devoted to follow-up and patient education. For example, during the provision of diabetes care, visits are very brief and focused on medication refills. Patients do not perceive they have the time or opportunity to discuss their concerns or have their learning needs addressed.[21] This lack of opportunity is believed to be a result of chronic staff shortages and heavy patient care demands.[25,26] This phenomenon is true throughout the health care system in Ethiopia but is especially impactful on patients in diabetic clinics. The result of these barriers is that knowledge and skills around self-practices contribute to the higher morbidity and mortality related to diabetes in Ethiopia.[8,14,19,27] This includes the lack of proper foot care practices that lead to a high amputation rate.

To overcome the challenges related to the lack of opportunity to provide foot care education, national and global initiatives emphasize the use of engaging and innovative education platforms. One such strategy is virtual simulation-based DFCE especially in resource-scarce settings.[28,29]

Virtual Simulation

Although simulation-based education has been used for decades, it is believed that simulation-based interventions will continue to advance into the 21st century as a result of Virtual Simulation Games (VSG).[30,31] With the availability of less expensive personal computers and simulation software, independent groups have developed simulator systems that have gained increasing attention in the areas of aviation, military training, and space flights.[32]

VSGs have been utilized in the aerospace industry since 1992 to assist in aeronautic engine design and amateur and commercial pilot training. This strategy has been proven cost-effective, safe, and engaging as a teaching modality.[32] The demonstrated benefit in the aviation business has created a great deal of interest and development with health care to adopt VSGs in establishing an engaging environment to augment medical education.[33]

Simulation intervention strategies have advanced considerably since the 2013 publication of the Healthcare Simulation Dictionary published by the Agency for Healthcare Research and Quality (AHRQ)[34] which provided a conceptual framework for simulation activities in health care including definition of terms and other technical guidance. A rigorously developed taxonomy aimed to create clarity and improve communication for health care simulationists in teaching, education, and research.[34] As a reputable resource for simulation terminology, the dictionary outlined the landscape of virtual simulation and identified virtual simulation games as "the recreation of reality depicted on a computer screen" that "injects humans in a central role by exercising motor control skills, decision skills, or communication skills" including "a simulation involving real people operating simulated systems".[34]

The purpose of virtual simulation is to provide engaging interactive media to support education that does not just provide entertainment but is useful to deliver patient care.[35,36] It has been suggested that the three integral components of virtual simulation gaming are simulation, learning, and gaming.[37] A virtual world creates access to engaging and interactive education anywhere, on any computer alternative or adjunct to traditional education.[34]

Available evidence continues to support the premise that VSG can enhance students' learning experience and improve the knowledge and skill related to the assigned tasks.[38] Virtual simulation-based education has been implemented in medical education to develop students' cognitive and psychomotor skills.[39,40] Virtual simulation promotes engagement, interaction, and feedback.[39] The underlying concept is that virtual simulation-based education being accessed through a variety of screen-based interactive and dynamic scenarios.

Despite recent popularity and the use in clinician training, virtual simulation-based education is relatively new in the area of patient education and little is known about its feasibility with regard to self-management education. There is a lack of evidence to support the use of VSG in direct patient education, especially in resource-limited settings where access to standardized and formal patient education programs are very limited and, in some cases, non-existent. To date, no published studies report the application of virtual simulation for patient education in sub-Saharan Africa. It is expected that this intervention will be well accepted by patients because of the gap in diabetes foot care education and the novelty of the application of technology to address this need.

In the current digital age and the emerging challenges related to a pandemic, the lack of research to support the full potential of VSG as a teaching modality for patients is concerning. The need for innovative diabetes self-management education resources is critical in Ethiopia where diabetes self-management education resources and personnel are limited, and the available education is delivered inconsistently.

Aim and Research Questions

Aim of the Study

This study aims to evaluate the feasibility of virtual simulation-based diabetes foot care education on foot care knowledge and practice/behaviour. To achieve this a virtual simulation game will be developed and implemented.

Research Questions

The primary question for this study is:

- In patients with diabetes mellitus II in Ethiopia, is virtual simulation-based diabetes foot care education a practical and acceptable intervention as compared to usual foot care education?

The secondary questions are:

- What is the impact of virtual simulation-based diabetes foot care education on diabetes foot self-care knowledge among patients with diabetes mellitus?
- What is the impact of virtual simulation-based diabetes foot care education on diabetes foot self-care behaviour among patients with diabetes mellitus?
- What is the impact of virtual simulation-based diabetes foot care education on diabetes foot self-care efficacy among patients with diabetes mellitus?

Methods

Study Design

This study uses a randomized controlled design to evaluate the feasibility of virtual simulation-based Diabetes Foot Care Education (DFCE) among adult patients with diabetes. The intervention group will receive a virtual simulation-based diabetes foot care education program in addition to usual diabetes care while the control group will continue receiving usual diabetes care only.

Study Setting

This study will be conducted at the University of Gondar tertiary referral hospital in Gondar, Ethiopia. Gondar city is located 727 km away from Addis Ababa, the capital city of Ethiopia. According to the 2007 Population and Housing Census of Ethiopia, the population of Gondar was 207,044.[41] The University of Gondar hospital is a 1000-bed capacity tertiary level referral hospital located at the heart of Gondar and currently serves as the tertiary specialty hospital for 7 million people.

The diabetic clinic at University of Gondar teaching and referral hospital was established in 1985 and patient documentation and registration was started 20 years ago. The clinic serves 2600 registered DM patients and among these 1312 are patients that have a diagnosis of type 2 diabetes. The clinic is open three days a week and on average, 200 patients with diabetes visit the clinic every week. Considering the number of patient encounters per week, it is estimated that participant recruitment will take one month.

Feasibility Testing

The overall framework for assessing the feasibility of virtual simulation-based DFCE will use the formal framework outlined by Bowen, Kreuter.[42] Briefly, this model outlines, eight key areas of focus for a feasibility study. These areas include acceptability, demand, implementation, practicality, adaptation, integration, expansion, and impact (limited-efficacy). Within these key areas, feasibility studies use study questions that are appropriate depending on the stage of development for the intervention (Figure 1).

The Bowen feasibility model emphasizes the importance of tailored approaches and study questions that specifically evaluate the feasibility of an intervention based on its current state of development. At the initial stage of developing an intervention, the main question is, “Can the intervention work?” Following this, and given evidence that the intervention might work, the second question is, “Does it work?” Thirdly, given the evidence that the intervention can be effective, the next question in the Brown feasibility model is, “Will it work?”. Evidence found in these stages of development is used to support the translation of the intervention into practice and develop clinical trials aimed at assessing the impact of the intervention.[42]

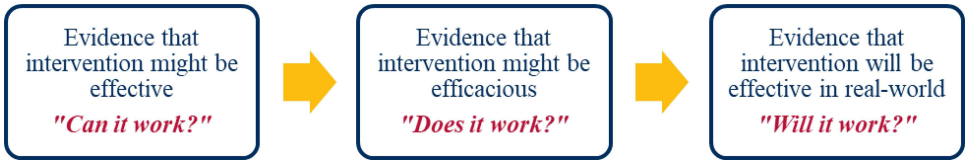

Figure 1 Areas of investigation for advancing phases of virtual simulation-based DFCE development and evaluation using randomized controlled feasibility study design.
Note: Data from.[42]

For the development of virtual simulation-based DFCE, the first two areas of investigation (Can it work and Does it work?) are most relevant as there have been few studies addressing the use of virtual simulation-based activities in DFCE. These two areas specifically address whether virtual simulation-based DFCE can work (acceptable and practical) and whether the intervention might be effective at improving patient-centered outcomes.

From the Bowen feasibility framework, this study will explore three critical areas: 1) acceptability, 2) practicality, and 3), impact (limited-efficacy testing). These areas were selected as they reflect the state of development of virtual simulation-based DFCE, the current state of diabetes education, and limited experience implementing diabetes education in Ethiopia.

Acceptability is a relatively common focus area for feasibility study and can be defined as users' willingness to use a given treatment, service, practice, or intervention.[43–45] In our study, acceptability looks at how patients with type 2 diabetes react to or perceive virtual simulation-based DFCE. Thus, acceptability will be measured using the perceived usefulness of the virtual simulation-based DFCE.

Practicality explores the extent to which the virtual simulation-based DFCE can be delivered and attempts to assess the ability of patients with type 2 diabetes to utilize virtual simulation-based DFCE. Less complex innovations such as virtual simulation games are easier to understand and less frustrating to use; thus, in our study, practicality will be measured using the usability of virtual simulation-based DFCE.[46]

Impact or limited-efficacy testing is testing the virtual simulation-based DFCE in a limited way by measuring the potential impact of virtual simulation-based DFCE on diabetes foot care knowledge and diabetes foot-care behaviour. Such feasibility study focus area is mostly conducted with intermediate rather than final outcomes and with shorter follow-up periods.

Enrollment Criteria

Inclusion criteria: adult patients (≥ 18 years), type 2 DM patients who are on diabetes follow-up at University of Gondar tertiary referral hospital.

Exclusion criteria: patients with type 1 diabetes or gestational diabetes, patients who previously attended any form of formal DSME program/ documented/ in the past three months, individuals with documented severe cognitive impairment, individuals with documented visual impairment that diminished their ability to navigate the game, terminally ill individuals, individuals without the ability to read or understand the Amharic consent documentation.

Participants' Recruitment and Screening

Potential participants will be informed about the trial through posters in the hospital's diabetes clinic. The nurses in the clinic will also speak to patients scheduled for their regular diabetes care appointment to identify interested patients. The names of interested patients will be released to the research assistant. The research assistant will meet with all interested patients in a private office after their diabetes follow-up visit to confirm their eligibility, explain the trial and obtain informed consent. All eligible patients will receive a verbal and written explanation of the trial, including risks and benefits of participating in the study, their right to withdraw from the trial at any time, that information collected will remain anonymous, and information will be stored securely to maintain confidentiality. Patients will be encouraged to ask questions prior to consenting to participate in the trial.

Usual Care

Participants in both groups will continue utilizing the usual follow-up diabetes care, which occurs every month. Usual care includes patients providing a morning fasting blood sample to assess their fasting blood sugar (FBS) and Hemoglobin A1c (HbA1c). Patients then wait at the hospital until the afternoon, and when they return to the diabetes clinic they have a brief 15 to 20 minutes verbal consultation in the afternoon with their general practitioner (doctor) in a large room full of other patients (around 20 patients at a time) and health professionals (around 8) including Nurses and Health Officers attending the diabetic clinic. During their consultation, they review their blood work (HbA1c and FBS) and have a brief discussion regarding diet, medication adherence, foot care, and other topics specific to the patient. Diabetes foot care education is minimal and consists of the type of shoes to wear and where to seek help when a diabetic foot ulcer develops. Under usual care, this discussion is typically brief, informal, and unstructured without clear goals or learning outcomes, without the use of teaching aids, and the information is driven by the physician's assessment of the most important topics for the patient.

Intervention

Participants will receive a virtual simulation-based DFCE sessions on seven topics (the reasons for inspecting one's feet, risk factors and prevention strategies of diabetic foot ulcer, how to wash and moisturize feet, comfortable sock and shoe choices, what to look for, and what to do during feet inspection, how to trim toenails, and how to maintain foot health) at University of Gondar computer lab for 30 minutes (Figure 2).

The virtual simulation game will be organized and developed in the Amharic language by the researcher along with diabetes expert nurses and simulation experts. The Amharic language is the Ethiopian official working language and it is a mother tongue language in the study site.

A computer lab will be set up at University of Gondar and participants will be invited to the established computer lab to explore each topic and go through the virtual simulation game. Then participants will be given a chance to ask questions before finishing the session and leaving the lab. Afterward, data collectors will interview participants about their reactions (what they like, challenges of utilizing the game, and what to improve) to the simulation game. To decrease the attrition rate and make the intervention session successful, the education session will be held on the date of the participants' routine follow-up visit.

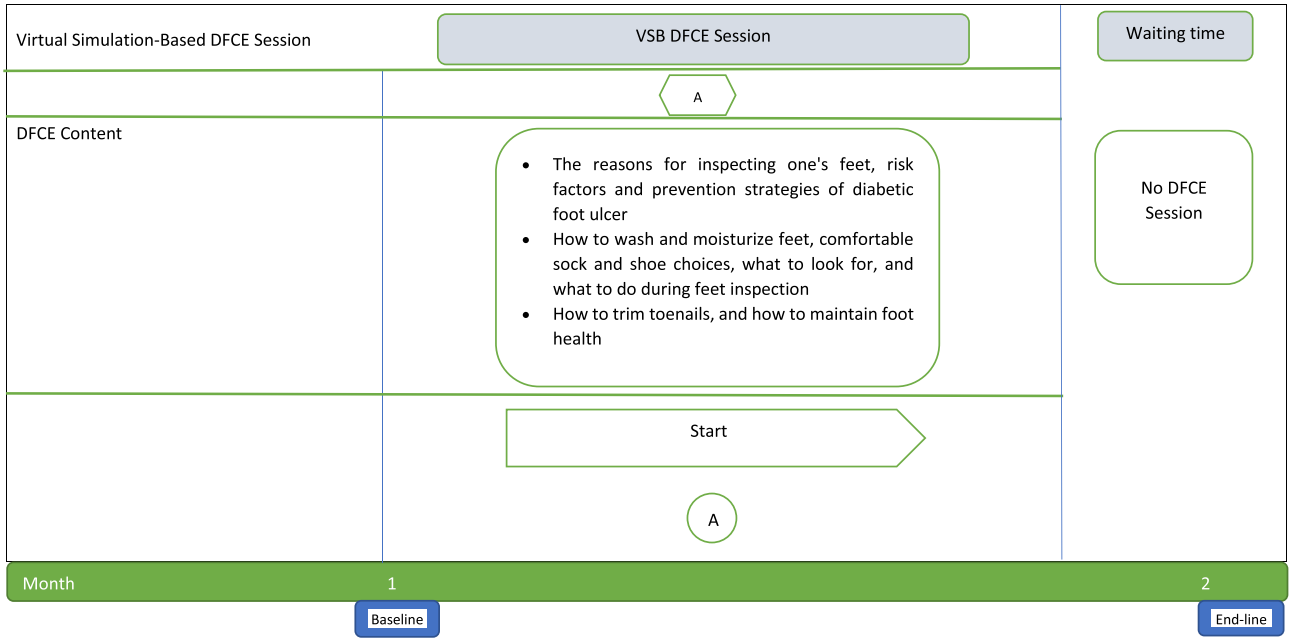

Figure 2 Virtual Simulation-Based DFCE sessions: The Feasibility and Potential Effectiveness of Simulation-Based Diabetic Foot Care Education/DFCE/ in adult patients with type 2 diabetes mellitus.

VSG Design and Creation

The design and content of virtual simulation-based DSME will be based on the the Diabetes Canada 2018 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada,[47] International Nursing Association for Clinical Simulation and Learning[48] Standards of Best Practice: Simulation Design,[48] International Diabetes Federation training manual for Sub-Saharan Africa,[49] and it will be customized to the local context using other evidence-informed practices in Ethiopia.[50] To customize and validate the content of the intervention protocol (virtual simulation-based DFCE), a consultation will be made with five experts working at University of Gondar Hospital diabetes clinic using open-ended questions. Based on the feedback, necessary changes and additions will be made to the content of the program.

The design and creation of the VSG will follow the Canadian Alliance of Nurse Educators using Simulation (CAN-Sim) VSG design process.[51,52] The creators will develop learning outcomes as the basis for pre-selected decision points with corresponding responses. The script of the video will be prepared by the principal investigator along with content experts to ensure accuracy and relevancy within the Ethiopian healthcare context. GoPro technology will be used to film the video portions of the game and include a standardized patient as a patient with diabetes. For the VSG content, Articulāte® Storyline 360 software will be used and the CAN-Sim software game template with pre-determined decision points and written rationales will be utilized. Content experts will include individuals in nursing education and diabetes care as well as content experts in simulation design, facilitation, and evaluation.

VSG Content

The VSG discusses and shows diabetes foot care. The contents and objectives are directed to educate patients with diabetes about diabetes foot care including the reasons for inspecting one's feet, risk factors and prevention strategies of diabetic foot ulcer, how to wash and moisturize feet, comfortable sock and shoe choices, what to look for, and what to do during feet inspection, how to trim toenails, and how to maintain foot health. The VSG will be filmed from the outside perspective where a nurse is educating a patient with diabetes which will provide an engaging experience for the learner which is a crucial component of VSG.[48]

A patient-nurse encounter with a realistic scenario and information will be provided. Following the VSG, the participant will be required to respond to a series of multiple-choice questions with response options. For each question, a different potential answer with a unique direction and information for foot care will be provided. If the learner chooses the correct answer, a video clip will be shown illustrating the results of their choice and a written rationale on why their response was correct. If learners respond correctly, then they will advance to the next video and decision point. If the learner's answer is incorrect, they will be shown a written rationale on why their decision is incorrect. Then learners will be redirected and given a chance to choose a more appropriate answer to the question.

Retention Strategy

In order to reduce loss to follow-up, participants will receive routine reminders about follow-up visits and the study visits will be coordinated with their routine clinic visits. Confidentiality will be ensured and potential barriers to attending appointments will be discussed.[53] Regular appointment dates will be arranged in a way to reduce information spillover between the intervention and control group participants. Thus, participants in the intervention and the comparison groups will visit the hospital on different days. At the end of the study, the virtual simulation-based DSME will be offered to the control group.

Study Variables

Dependent variables

Primary outcomes

- Acceptability of the virtual simulation-based DFCE
- Practicality of the virtual simulation-based DFCE

Secondary outcomes

- Diabetes foot care knowledge
- Diabetes foot care behaviour
- Diabetes foot self-care efficacy

Independent variables: Virtual Simulation-based Diabetes Foot Care Education

Covariates: Age, sex, marital status, living arrangement, residence, occupation, income, financial source for medication, education status, duration of diabetes, duration of follow-up.

Outcome Measures

Outcome measures will be collected using both interviewer-administered questionnaires and participant interviews. Data collectors will review the questionnaires for completeness and will ask participants if there are concerns or missing questions. Four data collectors will be trained on virtual simulation-based foot care education by the researcher to collect the data. The outcome measures will review the sociodemographic characteristics, anthropometric measurements and clinical and medical information, acceptability of the virtual simulation-based DFCE, practicality of virtual simulation-based DFCE, diabetes foot care knowledge, diabetes foot care behaviour, and diabetes foot self-care efficacy. Data collectors will not be informed about participants' group allocation. The data collection tool has seven components related to 1) socio-demographic characteristics, 2) clinical conditions, 3) acceptability, 4) practicality, 5, diabetes foot care knowledge, 6) diabetes foot care behaviour, and 7) diabetes foot self-care efficacy.

1. Socio-demographic Characteristics: Twelve questions (including age, sex, marital status, educational level, duration of diabetes) are prepared to gather the socio-demographic characteristics of participants. This will be collected before the intervention or usual care.
2. Acceptability: The Technology Acceptance Survey (TAS) measures acceptability, and practicability and will be used to assess virtual simulation-based DfcE.[38,54] The 16-item TAS is a brief self-report questionnaire that measures technology acceptance, ease of use and usefulness of the virtual simulation technology using a five-point Likert scale ranging from strongly disagree,[1] disagree,[2] neutral,[55] agree,[4] and strongly agree.[5,38] The perceived usefulness and the perceived ease of use subscales will be utilized to measure the acceptability and practicality of virtual simulation-based DFCE respectively. In a study of 80 patients with diabetes measuring the acceptance of health information technology, the reliability analysis revealed a Cronbach's α of 0.842 for the perceived usefulness and 0.929 for perceived ease of use subscales.[56,57] Similarly, in a sample of 30 technology users in Ethiopia, Hailu, Mammo[58] measured technology acceptability and usability which reported a Cronbach's α of 0.889 for perceived usefulness subscale and 0.846 for perceived ease of use subscale.
3. Diabetes Foot Care Knowledge: Diabetes foot care knowledge will be assessed with the Foot Care Knowledge (FCK) questionnaire. The FCK questionnaire was developed by Pollock, Unwin[59] and consists of 11 items. The FCK questions evaluate the respondent's foot care knowledge. Responses will be interpreted as " correct" or " incorrect" based on the questionnaire's answer key.[59] The maximum possible knowledge score will be 11 and can range from 1 to 11. In their study of individuals with diabetes,[60] documented that the FCK achieved a Content Validity Index (CVI) of 0.91. The FCK demonstrated acceptable test-retest reliability (r = 0.67–1).
4. Diabetes Foot Care Behaviour: Diabetes Foot Care Behaviour will be assessed with the 15-item Foot Self-Care Behaviour Scale (FSCBS).[61] The FSCBS is a brief self-report questionnaire that measures foot care behaviour. Patients will be asked to choose the most suitable response "never," "rarely," "sometimes," "often," and "always" to each question. Biçer and Enç[62] reported a Cronbach's alpha internal consistency of 0.83.
5. Diabetes Foot self-care efficacy: This will be measured with Foot Care Confidence Scale (FCCS). The tool consists of 12 items on a 5-point Likert scale (strongly not confident,[1] not confident,[2] moderately confident,[55] confident,[4] and strongly confident.[5] The score ranged from 12–60; a higher score indicates a higher level of

diabetes foot self-care efficacy. The tool has a content validity index of 100% and reliability (Cronbach's alpha) of 0.92.[63]

All the data collection tools have been translated from English to Amharic and then translated back to English to check the consistency. The Amharic version of the data collection tool will be used to collect data. The questionnaires will be pilot tested in 5 patients to see any challenges in filling out the questionnaires. How long it takes to fill the questionnaires will be determined and appropriate changes will be made based on the pilot test.

Sample Size

The sample size was calculated with the assumptions of increasing knowledge regarding foot care practices, as per the FCK questionnaire in the intervention group by 15% with a power of 80%, and one-sided test at 0.05 significance level. With the addition of 10% attrition rate, from the total 1312 adult Type 2 DM patients on active follow-up, we will recruit a total sample of 352 participants (176 in each arm). However, because this is a feasibility study, no formal sample size and power calculations are required to fully address the components of feasibility.[64] Post hoc analysis will be done to evaluate power. As a result, this study aims to recruit a convenience sample of 40 participants based on recommendations for feasibility study sample size calculations.[64,65]

Data Analysis

Data will be cleaned and coded before analysis. Data will be analyzed using the Statistical Package for Social Sciences (SPSS) version 25. Descriptive values such as frequencies, percentages, means, and standard deviations will be used to describe the sample and the study variables. Acceptability and practicality of virtual simulation-based DFCE will be analyzed using percentages, means, medians, and standard deviations. Pearson correlation will also be utilized between various socio-demographic variables (such as age, sex, and educational level) and the acceptability and practicality of virtual simulation-based DFCE to assess possible relationships between differences in these sociodemographic factors and changes in acceptability and practicality of the intervention.

An independent sample *t*-test and paired *t*-test will be used to compare the mean difference for all outcome variables (diabetes foot care knowledge, diabetes foot care behaviour, and diabetes foot self-care efficacy (proposed primary dependent variables of the future clinical trial). Factorial ANOVA will also be carried out for all outcomes. A subsequent post-hoc test will be utilized if a significant main effect or interactions are found (the detail is outlined in Table 1). P-values of less than 0.05 will be considered statistically significant. In addition to per-protocol analysis, an intention-to-treat analysis will be used to compare all participants who will receive the virtual simulation-based education as well as those who partially completed part of the sessions but failed to complete the whole sessions.[66] For missing values of outcome variables, multiple imputations will be used with the assumption of missing completely at random using five imputed data sets both at baseline and end-line.[67] The data collection instruments will be tested for reliability and validity. Cronbach's coefficient alpha will be used to measure the inter-item consistency reliability of the instruments.[68,69]

The qualitative data obtained through the face-to-face interviews will be analysed using a content analysis technique. Content analysis is

a systematic coding and categorizing approach used for exploring large amounts of textual information unobtrusively to determine trends and patterns of words used, their frequency, their relationships, and the structures and discourses of communication.[70]

An experienced Transcriptionist will transcribe the interview. The content analysis will follow the three phases: preparation, organizing, and reporting as outlined by Elo and Kyngäs.[71] During the preparation phase, the researcher will read and reread the transcribed interviews to familiarize with the data and obtain a sense of whole, select the unit of analysis (can be a word or a theme) in the data. The organizing phase includes open coding, creating categories (the lists of categories are grouped under higher-order headings), and abstraction.[71] Finally, reporting the study and presenting the results requires models, conceptual systems, conceptual map, or categories.

Table 1 Analysis Method for Each Study Question

Research Questions	Instrument	Analysis Method	Remarks
• Is virtual simulation-based DFCE an acceptable intervention among patients with diabetes in Ethiopia?	• Technology Acceptance Survey • (TAS) perceived usefulness subscale	• Descriptive statistics for perceived usefulness subscales of the Technology acceptance survey among intervention participants (percentages, means, medians, standard deviations) • Pearson correlation • Content analysis	
• Is virtual simulation-based DFCE practical among adult patients with diabetes?	• Technology Acceptance Survey • (TAS) perceived ease of use subscale • Fieldnotes	• Descriptive statistics for practicality/ usability/ subscales of the Technology acceptance survey among intervention participants (percentages, means, medians, standard deviations) • Content analysis	
• What is the potential impact of virtual simulation-based DFCE on diabetes foot care knowledge among patients with diabetes mellitus?	• Foot Care Knowledge (FCK) questionnaire	• Comparison of foot care knowledge comparing interventions and control groups. (Independent samples *t*-test) • Paired sample *t*-test • Factorial ANOVA • Post-hoc test	• Proposed primary dependent variables of the future clinical trial.
• What is the potential impact of virtual simulation-based DFCE on diabetes foot care behaviour among patients with diabetes mellitus?	• Foot Self-Care Behaviour Scale (FSCBS)	• Independent samples *t*-test • Paired sample *t*-test • Factorial ANOVA	
• What is the potential impact of virtual simulation-based DFCE on diabetes foot self-care efficacy among patients with diabetes mellitus?	• Foot Care Confidence Scale (FCCS)	• Independent samples *t*-test • Paired sample *t*-test • Factorial ANOVA	

Ensuring accuracy and avoiding misinterpretation of data is a central issue during the analysis of the data, thus, study participants will be contacted to verify the results as to their intended meaning. The researcher will also keep a journal of the reasoning processes behind the decisions made during the data analysis.

Study Population and Randomisation

All adult patients with type 2 diabetes who are registered to receive follow-up care and attend a regularly scheduled follow-up clinic visit at the University of Gondar Referral Hospital will be screened for eligibility to participate in the study. Following verification of meeting eligibility criteria, participants will be informed of the purpose of the study and informed consent will be obtained. Once a study participant provides consent to participate in the research, the research assistant (health officer) will call the diabetes nurse (randomization coordinator) and obtain the participant's study ID number and group allocation.

Group allocation will be assigned through a random assignment. Randomization of participants into this trial will be conducted in three steps: sequence generation, allocation through a concealed procedure, and final assignment and implementation of the study protocol (Kim & Shin, 2014). Simple randomization using a web-based generated sequence (www.randomization.com; Alberta, Canada) will be used to enroll eligible participants into the study groups.[72] A diabetes nurse working at Meraki Health Center (who is not part of the research team) will function as a third-party randomization coordinator and will refer to the randomly generated group assignment roster. To allow convenient access

to the randomization schedule, the diabetes nurse will use the previously generated assignment in sequential order and will refer to the randomization schedule and tell the research assistant (health officer) the participant's study ID number and group allocation to the study.[73–75] Data collectors (four nurses) will not be informed of participants' group allocation in order to avoid detection bias.

Data Collection Plan

The current study will follow six stages of data collection procedure.

Stage 1. A group of experts will meet to review the virtual simulation-based DFCE and the validation of the DFCE program. The process begins with the assembly of experts including a diabetes educator, diabetes nurses, pharmacist, and simulation-based education expert. Then the content of the DFCE program will be presented to the expert group for a review. After a content validation, the researcher and simulation experts will create and edit the games as required to make the simulation game as clear as possible.

Stage 2. Recruitment and training of the research team including data collectors will be carried out before the start of the study. During this stage, four nurses will be recruited to collect the data.

Stage 3. The consent process will include ethics approval from Queen's University and University of Gondar Research Ethics Boards. Participants will be approached and asked for voluntary participation during their regular clinic visits at a private office by the research assistant. Following ethics approval and informed consent, participants will be enrolled into the study groups. Participants that meet the inclusion criteria and consented to participate will be enrolled and followed for months as described in the study population and randomization section.

Stage 4. Once participants consented to be enrolled in the study, baseline data will be collected consisting of socio-demographic characteristics, clinical conditions, acceptability, practicality, diabetes foot care knowledge, diabetes foot care behavior, diabetes foot self-care efficacy using an interviewer-administered questionnaire, and participant interview.

Stage 5. Study participants will receive a virtual simulation-based DFCE for 30 minutes during their regularly scheduled follow-up appointments while patients in the control arm will receive usual care through their diabetes care team.

Stage 6. Post-intervention measurement will be held for both the intervention and control group following the final virtual simulation-based DFCE session.

Participants' interview. Following the completion of the post-intervention survey, semi-structured face-to-face individual interviews will be conducted. The purpose is to collect qualitative data that will inform the understanding of the mechanism of action of the intervention and the factors that influenced the acceptability and practicality of the intervention. Five participants will be purposefully selected. The interviews will be conducted by the researcher using a structured interview guide. The duration of the interview will be 20 and 30 minutes. The interviews will be audiotaped and transcribed verbatim immediately after each interview. Also, field notes will be made during the interview.

Ethical Considerations

Ethical review will be obtained from the Research Ethics Board of Queen's University and University of Gondar. The study will comply with the Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects. To create rapport and explore research collaboration in the study area, preliminary visits to key stakeholders will be performed by the research team to inform them of the purpose of the study, and the proposed timeline. Participants will be briefed about the purpose, the risks, and benefits of the study; informed consent will be secured (a written informed consent that will be translated into Amharic and signed consent will be returned before assigned to a group). Consent will include information on the voluntary nature of participation, their rights to withdraw at any time from the study, and their rights to declaim the interview data. Patients will be assured that their choice to decline will not in any way affect their care or any other services in the hospital. Researchers will answer any question raised and will further control and handle any unanticipated events that may arise during the study. Individuals willing to participate in the study will then be assessed based on the eligibility criteria before being recruited into the study and will be assigned a study number that will appear on the data collection form. To secure the privacy of participants, identifying information will not be made available to anyone not directly involved in the project. Questionnaires will be kept in a locked cabinet with physical

security to the storage room for a total of five years per Queen's University Policy. Then the questionnaires will be incinerated. The audio record from the face-to-face interviews will be transferred from the recorder to the encrypted computer and then deleted from the recorder once transcribed. The fieldnote will be converted to a digital format and stored as well in the encrypted computer.

Potential Limitations

There are several potential limitations to the conduct of this study. One potential limitation of our study includes study participant selection and participation. Study participants will be patients with type 2 diabetes mellitus with follow-up at University of Gondar hospital who present for day-long follow-up visits. Therefore, selecting both intervention and control groups from the same hospital may create contamination of information through verbal communication. However, it can be addressed by arranging the appointment dates of intervention and control group participants on different days.

Because participants are attending at a specialty hospital, there may be a potential social desirability bias in participants' responses. To avert the potential overestimation bias due to the self-reporting data collection questionnaire, a strict data collection procedure will be maintained. In addition, social desirability bias can be reduced by recruiting data collectors from outside the University of Gondar Hospital. Attrition from follow-up could present another challenge, but this will be addressed by offering participants a free lunch for participating.

Discussion

Interventions to enhance chronic disease self-management are an urgent priority[76] and are particularly required in low- and middle-income settings. Limited diabetes foot care knowledge and skill is a serious public health concern in Ethiopia partly due to inadequate attention and inaccessibility to diabetes foot care education. Effective foot care and prevention of foot complications can be supported by building knowledge and self-care skills of diabetes patients through structured, engaging, and innovative diabetes foot care education programs. Despite this need, pragmatic studies addressing the feasibility of contextualised diabetes foot care education programs are limited. Therefore, it is crucial to understand the feasibility and potential impact of virtual simulation-based DFCE in patients with type 2 diabetes mellitus. Thus, the proposed study will explore the feasibility of innovative, fun, and engaging patient education programs and improve the understanding of practical DFCE in a diversified socioeconomic context and help to create the foundation for the conceptualization of an effective diabetes education program.

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Disclosure

The authors declare they have no competing interests in this work.

References

1. Saeedi P, Petersohn I, Salpea P, et al. Global and regional diabetes prevalence estimates for 2019 and projections for 2030 and 2045: results from the International Diabetes Federation Diabetes Atlas, 9th edition. *Diabetes Res Clin Pract*. 2019;157:107843.
2. Cho NH, Shaw JE, Karuranga S, et al. IDF diabetes atlas: global estimates of diabetes prevalence for 2017 and projections for 2045. *Diabetes Res Clin Pract*. 2018;138:271–281. doi:10.1016/j.diabres.2018.02.023
3. International Diabetic Federation. IDF diabetes atlas. Belgium: International Diabetic Federation; 2017.
4. Nigatu T. Epidemiology, complications and management of diabetes in Ethiopia: a systematic review. *J Diabetes*. 2012;4(2):174–180. doi:10.1111/j.1753-0407.2011.00181.x
5. Edelman SV. Taking control of your diabetes: an innovative approach to improving diabetes care through educating, motivating, and making the connection between patients and health care providers. *Clin Diabetes*. 2017;35(5):333. doi:10.2337/cd17-0090
6. Norris SL, Lau J, Smith SJ, Schmid CH, Engelgau MM. Self-management education for adults with type 2 diabetes - A meta-analysis of the effect on glycemic control. *Diabetes Care*. 2002;25(7):1159–1171. doi:10.2337/diacare.25.7.1159

7. Powers MA, Bardsley J, Cypress M, et al. Diabetes self-management education and support in type 2 diabetes: a joint position statement of the American Diabetes Association, the American Association of Diabetes Educators, and the Academy of Nutrition and Dietetics. *Diabetes Educ*. 2017;43(1):40–53. doi:10.1177/0145721716689694
8. Funnell MM, Brown TL, Childs BP, et al. National standards for diabetes self-management education. *Diabetes Care*. 2012;35 Suppl 1 (Supplement_1):S101–S8. doi:10.2337/dc12-s101
9. Fu X-L, Ding H, Miao W-W, Mao C-X, Zhan M-Q, Chen H-L. Global recurrence rates in diabetic foot ulcers: a systematic review and meta-analysis. *Diabetes Metab Res Rev*. 2019;35(6):e3160. doi:10.1002/dmrr.3160
10. Zha M-L, Cai J-Y, Chen H-L. A bibliometric analysis of global research production pertaining to diabetic foot ulcers in the past ten years. *J Foot Ankle Surg*. 2019;58(2):253–259. doi:10.1053/j.jfas.2018.08.052
11. Jiang F-H, Liu X-M, Yu H-R, Qian Y, Chen H-L. The incidence of depression in patients with diabetic foot ulcers: a systematic review and meta-analysis. *Int J Low Extrem Wounds*. 2020;1534734620929892. doi:10.1177/1534734620929892
12. Dinesh PV, Kulkarni AG, Gangadhar NK. Knowledge and self-care practices regarding diabetes among patients with Type 2 diabetes in Rural Sullia, Karnataka: a community-based, cross-sectional study. *J Fam Med Prim Care*. 2016;5(4):847–852. doi:10.4103/2249-4863.201176
13. Hasina Akhter C, Kaniz F, Hossain S, et al. Knowledge and self-care practice regarding diabetes among type 2 diabetics: experience from a non-profit hospital chain in Bangladesh. *Int J Diabetes Dev Ctries*. 2017;38:1–8.
14. Mariye T, Tasew H, Teklay G, Gerensea H, Daba W. Magnitude of diabetes self-care practice and associated factors among type two adult diabetic patients following at public Hospitals in central zone, Tigray Region, Ethiopia, 2017. *BMC Res Notes*. 2018;11(1):380. doi:10.1186/s13104-018-3489-0
15. Aschalew AY, Yitayal M, Minyihun A, Bisetegn TA. Self-care practice and associated factors among patients with diabetes mellitus on follow up at University of Gondar Referral Hospital, Gondar, Northwest Ethiopia. *BMC Res Notes*. 2019;12(1):591. doi:10.1186/s13104-019-4630-4
16. Seid A, Tsige Y. Knowledge, practice, and barriers of foot care among diabetic patients attending Felege Hiwot Referral Hospital, Bahir Dar, Northwest Ethiopia. *Adv Nurs*. 2015;2015:934623. doi:10.1155/2015/934623
17. Beran D, Yudkin JS. Diabetes care in sub-Saharan Africa. *Lancet*. 2006;368(9548):1689–1695. doi:10.1016/S0140-6736(06)69704-3
18. Feleke Y, Enquselassie F. An assessment of the health care system for diabetes in Addis Ababa, Ethiopia. *Ethiop J Health Dev*. 2005;19 (3):203–210.
19. Chali SW, Salih MH, Abate AT. Self-care practice and associated factors among diabetes mellitus patients on follow up in Benishangul Gumuz Regional State Public Hospitals, Western Ethiopia: a cross-sectional study. *BMC Res Notes*. 2018;11(1):833. doi:10.1186/s13104-018-3939-8
20. Abejew AA, Belay AZ, Kerie MW. Diabetic complications among adult diabetic patients of a tertiary hospital in Northeast Ethiopia. *Adv Public Health*. 2015;2015:290920. doi:10.1155/2015/290920
21. Bishu KG, Jenkins C, Yebyo HG, Atsbha M, Wubayehu T, Gebregziabher M. Diabetes in Ethiopia: a systematic review of prevalence, risk factors, complications, and cost. *Obesity Med*. 2019;15:100132. doi:10.1016/j.obmed.2019.100132
22. Wondwossen A, Reja A, Amare A. Diabetic foot disease in Ethiopian patients: a Hospital Based Study. *Ethiop J Health Dev*. 2011;25:17–21.
23. Gudina EK, Amade ST, Tesfamichael FA, Ram R. Assessment of quality of care given to diabetic patients at Jimma University Specialized Hospital diabetes follow-up clinic, Jimma, Ethiopia. *BMC Endocr Disord*. 2011;11(1):19. doi:10.1186/1472-6823-11-19
24. Deressa W, Azazh A. Attitudes of undergraduate medical students of Addis Ababa University towards medical practice and migration, Ethiopia. *BMC Med Educ*. 2012;12(1):68. doi:10.1186/1472-6920-12-68
25. Federal Democratic Republic of Ethiopia Ministry of Health [FDRMOH]. Addressing the impact of noncommunicable diseases and injuries in Ethiopia. Ethiopia Federal Democratic Republic of Ethiopia Ministry of Health; 2018.
26. Federal Democratic Republic of Ethiopia Ministry of Health. HSTP health sector transformation plan 2015/16-2019/20 (2008-2012 EFY). Addis Ababa: Federal Democratic Republic of Ethiopia Ministry of Health; 2015.
27. Kassahun T, Eshetie T, Gesesew H. Factors associated with glycemic control among adult patients with type 2 diabetes mellitus: a cross-sectional survey in Ethiopia. *BMC Res Notes*. 2016;9(1):78. doi:10.1186/s13104-016-1896-7
28. Sperl-Hillen J, O'Connor P, Ekstrom H, et al. Using simulation technology to teach diabetes care management skills to resident physicians. *J Diabetes Sci Technol*. 2013;7(5):1243–1254. doi:10.1177/193229681300700514
29. Johnson C, Feenan K, Setliff G, et al. Building a virtual environment for diabetes self-management education and support. *Int J Virtual Communities Soc Netw*. 2013;5(3):111359. doi:10.4018/ijvcsn.2013070105
30. Schrier K. Using augmented reality games to teach 21st century skills. Boston, Massachusetts: ACM SIGGRAPH 2006 Educators program; Association for Computing Machinery; 2006: 15.
31. Lateef F. Simulation-based learning: just like the real thing. *J Emerg Trauma Shock*. 2010;3(4):348–352. doi:10.4103/0974-2700.70743
32. Stone RJ, Panfilov PB, Shukshunov VE. Evolution of aerospace simulation: from immersive Virtual Reality to serious games. Proceedings of 5th International Conference on Recent Advances in Space Technologies - RAST2011; 9–11 June 2011.
33. Kalkman CJ. Serious play in the virtual world: can we use games to train young doctors? *J Grad Med Educ*. 2012;4(1):11–13. doi:10.4300/JGME-D-11-00309.1
34. Downing D, Chang TP, Robertson JM, Anderson M, Diaz DA, Spain AE; Eds.; the Terminology and Concepts Working Group. *Healthcare Simulation Dictionary*. 2nd ed. Rockville, MD: Agency for Healthcare Research and Quality; 2020.
35. Padilha JM, Machado PP, Ribeiro A, Ramos J, Costa P. Clinical virtual simulation in nursing education: randomized controlled trial. *J Med Internet Res*. 2019;21(3):e11529–e. doi:10.2196/11529
36. De Freitas S, Rebolledo-Mendez G, Liarokapis F, Magoulas G, Poulovassilis A. Learning as immersive experiences: using the four-dimensional framework for designing and evaluating immersive learning experiences in a virtual world. *Br J Educ Technol*. 2010;41(1):69–85. doi:10.1111/j.1467-8535.2009.01024.x
37. Petit Dit Dariel OJ, Raby T, Ravaut F, Rothan-Tondeur M. Developing the Serious Games potential in nursing education. *Nurse Educ Today*. 2013;33(12):1569–1575. doi:10.1016/j.nedt.2012.12.014
38. Verkuyl M, Romaniuk D, Atack L, Mastrilli P. Virtual gaming simulation for Nursing education: an experiment. *Clin Simul Nurs*. 2017;13 (5):238–244. doi:10.1016/j.ecns.2017.02.004
39. Foronda CL, Fernandez-Burgos M, Nadeau C, Kelley CN, Henry MN. Virtual simulation in nursing education: a systematic review spanning 1996 to 2018. *Simul Healthc*. 2020;15(1):46–54. doi:10.1097/SIH.0000000000000411

40. Christopoulos A, Conrad M, Shukla M. Increasing student engagement through virtual interactions: how? *Virtual Real*. 2018;22(4):353–369. doi:10.1007/s10055-017-0330-3
41. Central statistical agency Ethiopian population and housing census report. Central Statistical Agency; 2007. Available from: http://www.csa.gov.et/census-report/complete-report/census-2007. Accessed March 3, 3022.
42. Bowen DJ, Kreuter M, Spring B, et al. How we design feasibility studies. *Am J Prev Med*. 2009;36(5):452–457. doi:10.1016/j.amepre.2009.02.002
43. Fischer AJ, Dart EH, Leblanc H, Hartman KL, Steeves RO, Gresham FM. An investigation of the acceptability of videoconferencing within a school-based behavioral consultation framework. *Psychol Sch*. 2016;53(3):240–252. doi:10.1002/pits.21900
44. Nadal C, Sas C, Doherty G. Technology acceptance in mobile health: scoping review of definitions, models, and measurement. *J Med Internet Res*. 2020;22(7):e17256. doi:10.2196/17256
45. Proctor E, Silmere H, Raghavan R, et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. *Adm Policy Ment Health*. 2011;38(2):65–76. doi:10.1007/s10488-010-0319-7
46. Wallace LG, Sheetz SD. The adoption of software measures: a technology acceptance model (TAM) perspective. *Inf Manag*. 2014;51(2):249–259. doi:10.1016/j.im.2013.12.003
47. Embil JM, Albalawi Z, Bowering K, Trepman E. Foot Care. *Can*. 2018;42:S222–S7.
48. INACSL Standards Committee. INACSL. Standards of best practice: simulationsm participant evaluation. *Clin Simul Nurs*. 2016;12:S26–S9. doi:10.1016/j.ecns.2016.09.009
49. International standards for education of diabetes health professionals [Internet]; 2015. Available from: https://www.idf.org/e-library/%20education/63-international-standards-for-education-of-diabetes-healthprofessionals.html. Accessed March 3, 3022.
50. Hailu FB, Hjortdahl P, Moen A. Nurse-led diabetes self-management education improves clinical parameters in Ethiopia. *Front Public Health*. 2018;6(302). doi:10.3389/fpubh.2018.00302
51. Keys E, Luctkar-Flude M, Tyerman J, Sears K, Woo K. Developing a virtual simulation game for nursing resuscitation education. *Clin Simul Nurs*. 2020;39:51–54. doi:10.1016/j.ecns.2019.10.009
52. Luctkar-Flude M, Tyerman J, Ziegler E, et al. Developing a sexual orientation and gender identity nursing education toolkit. *J Contin Educ Nurs*. 2020;51(9):412–419. doi:10.3928/00220124-20200812-06
53. Zweben A, Fucito LM, O'Malley SS. Effective strategies for maintaining research participation in clinical trials. *Drug Inf J*. 2009;43(4):459–467. doi:10.1177/009286150904300411
54. Zhang Y, Liu C, Luo S, et al. Factors influencing patients' intentions to use diabetes management apps based on an extended unified theory of acceptance and use of technology model: web-based survey. *J Med Internet Res*. 2019;21(8):e15023–e. doi:10.2196/15023
55. Wahr JA, Abernathy JH 3rd, Lazarra EH, et al. Medication safety in the operating room: literature and expert-based recommendations. *Br J Anaesth*. 2017;118(1):32–43. doi:10.1093/bja/aew379
56. Shahrabi MA, Ahaninjan A, Nourbakhsh H, Ashlubolagh MA, Abdolmaleki J, Mohamadi M. Assessing psychometric reliability and validity of Technology Acceptance Model (TAM) among faculty members at Shahid Beheshti University. *Manag Sci Lett*. 2013;3:2295–2300. doi:10.5267/j.msl.2013.07.014
57. Isma B, Ahmad E, Ahlan AR. Reliability and validity of a questionnaire to evaluate diabetic patients' intention to adopt health information technology: a pilot study. *J Theor Appl Inf Technol*. 2015;72:253–264
58. Hailu M, Mammo Y, Ketema M. Internet acceptance and use model in Ethiopian agriculture education and research: the case of two universities. *Int J Sci Technol Educ Res*. 2016;7(4):35–48. doi:10.5897/IJSTER2016.0349
59. Pollock RD, Unwin NC, Connolly V. Knowledge and practice of foot care in people with diabetes. *Diabetes Res Clin Pract*. 2004;64(2):117–122. doi:10.1016/j.diabres.2003.10.014
60. Indrayana S, Guo S-E, Lin C-L, Fang S-Y. Illness perception as a predictor of foot care behavior among people with type 2 diabetes mellitus in Indonesia. *J Transcult Nurs*. 2018;30(1):17–25. doi:10.1177/1043659618772347
61. Biçer EK, Enç N. Evaluation of foot care and self-efficacy in patients with diabetes in Turkey: an interventional study. *Int J Diabetes Dev Ctries*. 2016;36(3):334–344. doi:10.1007/s13410-016-0464-y
62. Biçer E, Enç N. Validity and reliability of the Turkish adaptation of the foot self care behaviour scale. *Diyabet, Obezite ve Hipertansiyonda Hemsirelik Forumu Dergisi*. 2014;6(2):35–39.
63. Sloan HL. Developing and testing of the foot care confidence scale. *J Nurs Meas*. 2002;10(3):207–218. doi:10.1891/jnum.10.3.207.52564
64. Billingham SAM, Whitehead AL, Julious SA. An audit of sample sizes for pilot and feasibility trials being undertaken in the United Kingdom registered in the United Kingdom Clinical Research Network database. *BMC Med Res Methodol*. 2013;13(1):104. doi:10.1186/1471-2288-13-104
65. Sim J, Lewis M. The size of a pilot study for a clinical trial should be calculated in relation to considerations of precision and efficiency. *J Clin Epidemiol*. 2012;65(3):301–308. doi:10.1016/j.jclinepi.2011.07.011
66. McCoy CE. Understanding the intention-to-treat principle in randomized controlled trials. *West J Emerg Med*. 2017;18(6):1075–1078. doi:10.5811/westjem.2017.8.35985
67. Jakobsen JC, Gluud C, Wetterslev J, Winkel P. When and how should multiple imputation be used for handling missing data in randomised clinical trials – a practical guide with flowcharts. *BMC Med Res Methodol*. 2017;17(1):162. doi:10.1186/s12874-017-0442-1
68. Woo K. *Polit & Beck: Canadian Essentials of Nursing Research*. 4th ed. Philadelphia: Wolters Kluwer; 2019.
69. Tavakol M, Dennick R. Making sense of Cronbach's alpha. *Int J Med Educ*. 2011;2:53–55. doi:10.5116/ijme.4dfb.8dfd
70. Vaismoradi M, Turunen H, Bondas T. Content analysis and thematic analysis: implications for conducting a qualitative descriptive study. *Nurs Health Sci*. 2013;15(3):398–405. doi:10.1111/nhs.12048
71. Elo S, Kyngäs H. The qualitative content analysis process. *J Adv Nurs*. 2008;62(1):107–115. doi:10.1111/j.1365-2648.2007.04569.x
72. Kim J, Shin W. How to do random allocation (randomization). *Clin Orthop Surg*. 2014;6(1):103–109. doi:10.4055/cios.2014.6.1.103
73. Dettori J. The random allocation process: two things you need to know. *Evid Based Spine Care J*. 2010;1(3):7–9. doi:10.1055/s-0030-1267062
74. Haag U. Technologies for automating randomized treatment assignment in clinical trials. *Drug Inf J*. 1998;32(1):7–11. doi:10.1177/009286159803200102
75. Torgerson DJ, Roberts C. Understanding controlled trials concealment. *BMJ*. 1999;319(7206):375–376.
76. Hill-Briggs F. Problem solving in diabetes self-management: a model of chronic illness self-management behavior. *Ann Behavior Med*. 2003;25(3):182–193. doi:10.1207/S15324796ABM2503_04