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Pre-registered Study Protocols

PRE-REGISTERED STUDY PROTOCOLS

Effect of community-based lifestyle education intervention to reduce cardiovascular diseases risk factors among vulnerable population in Dodoma city, Tanzania: a cluster randomized controlled trial study protocol

Nyasiro S. Gibore [1,*], Mariam J. Munyogwa [2], Secilia K. Ng'weshemi[2] and Ainory P. Gesase[2]

[1]School of Nursing and Public Health, The University of Dodoma, P.O. Box 395, Dodoma, Tanzania and [2]School of Medicine and Dentistry, The University of Dodoma, P.O. Box 395, Dodoma, Tanzania

*Correspondence address. School of Nursing and Public Health, The University of Dodoma, P.O. Box 395, Dodoma, Tanzania. E-mail: nyasiro2@gmail.com

Abstract

Tanzania is experiencing the rise of cardiovascular diseases (CVDs) and associated risk factors including hypertension, obesity and diabetes mellitus. Health education and healthy lifestyle promotion is an effective approach toward primary prevention of the risk factors and can be achieved through community-based intervention. The objective of this protocol is to test the effectiveness of community-based lifestyle education intervention in reducing CVDs risk factors among vulnerable population in Dodoma City. This protocol is designed as a cluster-randomized controlled trial with a quantitative approach in which participants aged from 31 years will be assigned randomly to a control or intervention group. A total of 800 participants will be recruited in the study. The study will consist of six stages (baseline, first to fourth follow-up, and end-line surveys) in 6 months for both the intervention and the control group. The intervention will be implemented twice-monthly for the first 3 months, then monthly for the last 3 months. In each stage, participants from all groups will be measured for biological and behavioral CVDs risk factors. Health education and a healthy lifestyle promotion for prevention of CVDs risk factors will be provided to the intervention group only during each stage. The main outcome measures will be changes in body weight, blood pressure, blood glucose, dietary habits, and physical exercise in the intervention compared with the control group. Independent and paired *t*-tests will be employed to make comparisons between and within groups. *P*-values of less than 0.05 will be considered statistically significant.

Keywords: cardiovascular diseases risk factors; healthy lifestyle promotion; health education on health lifestyle; community-based lifestyle intervention; dietary habits; physical exercises; biological risk factors; behavioral risk factors

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Introduction

Cardiovascular diseases (CVDs) is a general term for conditions affecting the heart and blood vessels [1]. The most common CVDs include coronary heart disease, stroke, peripheral arterial diseases, and aortic diseases [1]. The risk factors associated with CVDs can be categorized into modifiable and non-modifiable risk factors. The modifiable risk factors include elevated blood pressure, dyslipidemia, elevated blood sugar, overweight and obesity, smoking, excessive alcohol intakes, unhealthy diet, and physical inactivity [2]. The non-modifiable risk factors include family history of CVDs, age, and gender [1]. The increasing burden of CVDs is driven mainly by four modifiable risk factors, namely unhealthy dietary habits characterized by consumption of high energy-dense foods, physical inactivity, excessive alcohol drinking, and smoking [3].

CVDs are the leading cause of death and disability globally [4]. It is projected that deaths associated with CVDs will reach more than 24 million deaths by 2030 if appropriate measures are not undertaken [4]. About 80% of these deaths are expected to occur in low- and middle-income countries [5]. Many sub-Saharan African (SSA) countries are already experiencing the rise of CVDs and associated risk factors, including hypertension, obesity, diabetes mellitus, and dyslipidemia [6]. For instance in Tanzania the available data indicate increased prevalence of hypertension, obesity, diabetes, and metabolic syndrome [7–10] and the rate of deaths associated with CVDs had increased from 9% to 13% between 2012 and 2016 [11, 12].

Health system in Tanzania has been implementing different CVDs interventions including screening and treatment of CVDs and provision of education on healthy eating and physical exercise. However, many of these interventions are secondary, offered to patients who attend to the health care facilities. Those who misses opportunity to visit health care facilities they are not benefiting with these interventions which may result to delays in taking appropriate action to prevent the development of CVDs risk factors. CVDs related mortality can be reduced by using effective lifestyle interventions focusing on reduction of population risk factors such as high blood pressure, smoking, hypercholesterolemia, and diabetes [13]. This has been tested in few countries, for example, in Finland, lifestyle interventions accounted for 53–72% of the decline in coronary heart disease mortality [14] while in England and Wales, the reduction of population risk factors accounted for 58% of the decline in CVDs mortality [15]. In Tanzania, effective primary interventions of CVDs that address lifestyle modifications at community-level are still limited especially when compared with the rate of increase of these diseases. These interventions are highly required in this country where there is a shortage of both financial and human resources for the delivery of healthcare services to serve the double burden of communicable and non-communicable diseases (NCDs). Therefore, this study is designed to assess the effectiveness of a community-based lifestyle intervention as a primary prevention to reduce the risks of developing CVDs risk factors among vulnerable population in Dodoma City. Specifically, the objectives of this study are

- To determine the prevalence of the biological risk factors for developing CVDs among vulnerable population in Dodoma City.
- To determine the prevalence of behavioral risk factors for developing CVDs among vulnerable population in Dodoma City.
- To assess the effectiveness of community-based lifestyle education intervention to reduce biological risk factors for developing CVDs among vulnerable population in Dodoma City.
- To assess the effectiveness of community-based lifestyle education intervention to reduce behavioral risk factors for developing CVDs among vulnerable population in Dodoma City.
- To assess the effectiveness of community-based lifestyle education intervention on knowledge of CVDs risk factors among vulnerable population in Dodoma City.

The findings of this study will have policy implication about the effect of community-based health education and healthy lifestyle promotion for the primary prevention of CVDs risk for vulnerable population especially now when the Tanzanian government is emphasizing on primary prevention of NCDs.

Materials and methods

Study area

This study will be conducted in Dodoma City. Dodoma City is found in Dodoma Region which is located in central and semi-arid zone of Tanzania. The city is also the capital of Dodoma Region and the national capital of Tanzania. Dodoma City has been selected purposively for this study because of high rate of urbanization, since the Tanzania government officially shifted most of its offices from Dar es Salaam to Dodoma City there is a lot of development activities in the city. These developments have resulted in increase of employment opportunities, leading to migration of people from all over the country and beyond to the City. According to the report of Economic Survey [16], the number of commuter buses in Dodoma Region had increased by 85.2%. Consequently, all these has led to change in lifestyle to cope with the rate of modernization. Previous studies in Dodoma had shown high prevalence of overweight and obesity among children and adults (11.8% and 24.88%, respectively) [17, 18]. According to the population projection of the 2017, the city is estimated to have a population of 459,350. Administratively, the city has a total of 37 wards, only four wards will be involved in the study. The average annual population growth rate is 2.1% [19]. The main staple food includes maize, sorghum, and millet.

Study design and population

This study will use community-based cluster-randomized controlled trial with two arms (intervention and control groups). The study will employ quantitative study approach. All adults residents of Dodoma City aged from 31 years and above, who is expected to live in the study area until the end of the study and who will agree and sign the consent will be included in the study. Pregnant women, known cases of hypertension and diabetes, severely ill patients, and mentally ill individuals will be excluded from the study.

Intervention

The intervention package will comprise the following components: (1) Health education and a healthy lifestyle promotion. (2) Measurement of biological risk factors for developing CVDs (body weight, body height, waist circumference (WC), blood pressure, and fasting blood glucose). (3) Measurement of behavioral risk factors for developing CVDs (dietary habits, smoking, alcohol consumption, and physical exercises).

(1) Health education and healthy lifestyle promotion

Researchers have developed the education material that will raise awareness on CVDs risk factors and promote healthy

lifestyles (Supplementary File S1). The development of educational material was based on exhaustive review of literature from previous studies [20–24], the objective of the study, and relevant local factors related to research questions. The material was then translated to local language (Swahili) to make the interview to be understood well by participants. This material will be delivered to each study participants in the interventional group after the baseline survey.

Researchers and research assistants will conduct health education to participants during household visit to raise awareness on CVDs risk factors and promote healthy lifestyles. Health education will focus on information pertaining to the harmful effects of CVDs risk factors; maintaining healthy body weight, smoking cessation, reduction of excessive alcohol drinking, reduction of salt intake, reducing fat intakes, increased consumption of fruits and green leafy vegetables, reduce consumption of red meat, and use of unrefined cereals. Participants will also be provided with the brochures on CVDs risk factors for their reference. Brochures will consist of illustrative information which will be easy to follow incase participant is not able to read. Health education and healthy lifestyle promotion will be given twice in the first 3 months and then monthly for the second 3 months. For ethical consideration, the control group will receive health education and healthy lifestyle promotion at the end of the study.

(2) Measurement of biological risk factors

The biological risk factors will be measured as follows:

Body weight and height. Body weight will be measured by using an electronic bathroom weighing scale (SECCA-West Germany) with minimal clothes. Height will be measured without shoes, using the stadiometer that will be fixed against the wall. Both measurements will be taken in duplicates and the average will represent the participant's weight/height. Body weight will be recorded to the nearest 0.1 kg. Height will be recorded to the nearest 0.5 cm. Body mass index (BMI) will be calculated by dividing the weight of the subject (kg) by square of the height (m^2). BMI will be classified as $<$ 18.5= underweight, 18.5–24.9 = normal, 25–29.9 = overweight, and $\geq$30 = obesity [25].

Waist circumference. WC will be measured using the guideline of WHO protocol for measuring waist and hip circumference [26]. WC will be taken approximately at the midpoint between the lower margin of the last palpable rib and the top of the iliac crest. During taking of measurements, the tape measure will be allowed only to snug the body and maintained at parallel position with the floor and never pulled so tight to constrict the body. During measurements, participants will be required to stand erect with their weights evenly distributed on both feet. The participants will be requested to relax by breathing out gently. Measurements will be taken twice and an average will be used to represent the participant's WC.

Blood pressure. Blood pressure will be measured by using a sphygmomanometer and recorded in millimeters of mercury (mmHg). Measurements will be done in duplicates at an interval of at least 5 min and the average will represent the participant's blood pressure. Measurement will be taken while the participant is seated on a chair with her/his back supported and feet flat on the ground with their arms resting on a table. The participant will be asked to empty bladder before the measurement. Blood pressure will be defined as elevated blood pressure when systolic blood pressure will be $\geq$140 mmHg and/or diastolic blood pressure $\geq$90 mmHg [27]. Participants found to have elevated blood pressure will be referred to their respective nearby health facilities for confirmation of diagnosis and further management.

Blood glucose. Blood glucose will be measured after overnight fasting by using a Glucoplus glucometer machine. A drop of blood from finger prick will be used to measure blood glucose. Participant will be given fasting instructions a day prior to testing. Blood glucose will be defined as elevated blood glucose $\geq$7 mmol/L and normal blood glucose $<$7 mmol/L [28]. After the test results, those found with elevated blood glucose will be referred to nearby health facilities for confirmation of diagnosis and further management.

(3) Measurement of behavioral risk factors

The behavioral risk factors will be measured by using a questionnaire which will be adapted from WHO-steps survey [29]. The questionnaire will measure the following: physical exercises, smoking, alcohol intake, and dietary habit (specifically salt intake, fat intake, consumption of fruits and green leafy vegetables, consumption of red meat, and use of unrefined cereals).

Outcome measures

(i) Primary outcome

The primary outcome measure is change in the proportion of overweight/obesity at 6 months in the intervention group compared with control group. The study aims to detect a proportional change in body BMI of $\geq$20 percentage in the intervention group compared with control group.

(ii) Secondary outcomes

Secondary outcome measures will include: (1) change from baseline in the proportion of individuals at high risk for CVDs (elevated blood glucose, elevated blood pressure) for $\geq$20%; (2) change from baseline in the proportion of smoking, alcohol intake, unhealthy dietary habits, and physical inactivity; and (3) change in CVDs knowledge at 6 months after a health education and healthy lifestyle promotion.

Sample size calculation and sampling technique

The sample size will be calculated to provide a 90% power to detect a proportional change in body BMI of $\geq$20% between the intervention and control wards at an alpha level of 5% and 95% confidence interval, an expected drop-out of 20%, an intercluster correlation of 0.03, and a standard deviation of 0.84, with the ratio of intervention to control of 1:1. The minimum sample size will be 400 participants per group of two wards. Therefore, the total sample size for the study will be 800 participants from four wards (two wards for intervention and two wards for control). The study groups will be matched in the ratio of 1:1. A multistage sampling will be used. A list of names of all 37 wards from the city will be obtained from the census document [19]. From the list, four wards will be selected for the study by simple random sampling using lottery method. Two wards will be for interventional group and another two for control group. From each ward all households with adults aged 31 years and above will be identified by the help of respective street leaders and a list of all households with eligible participants will be prepared. Systematic sampling method will be used to select household

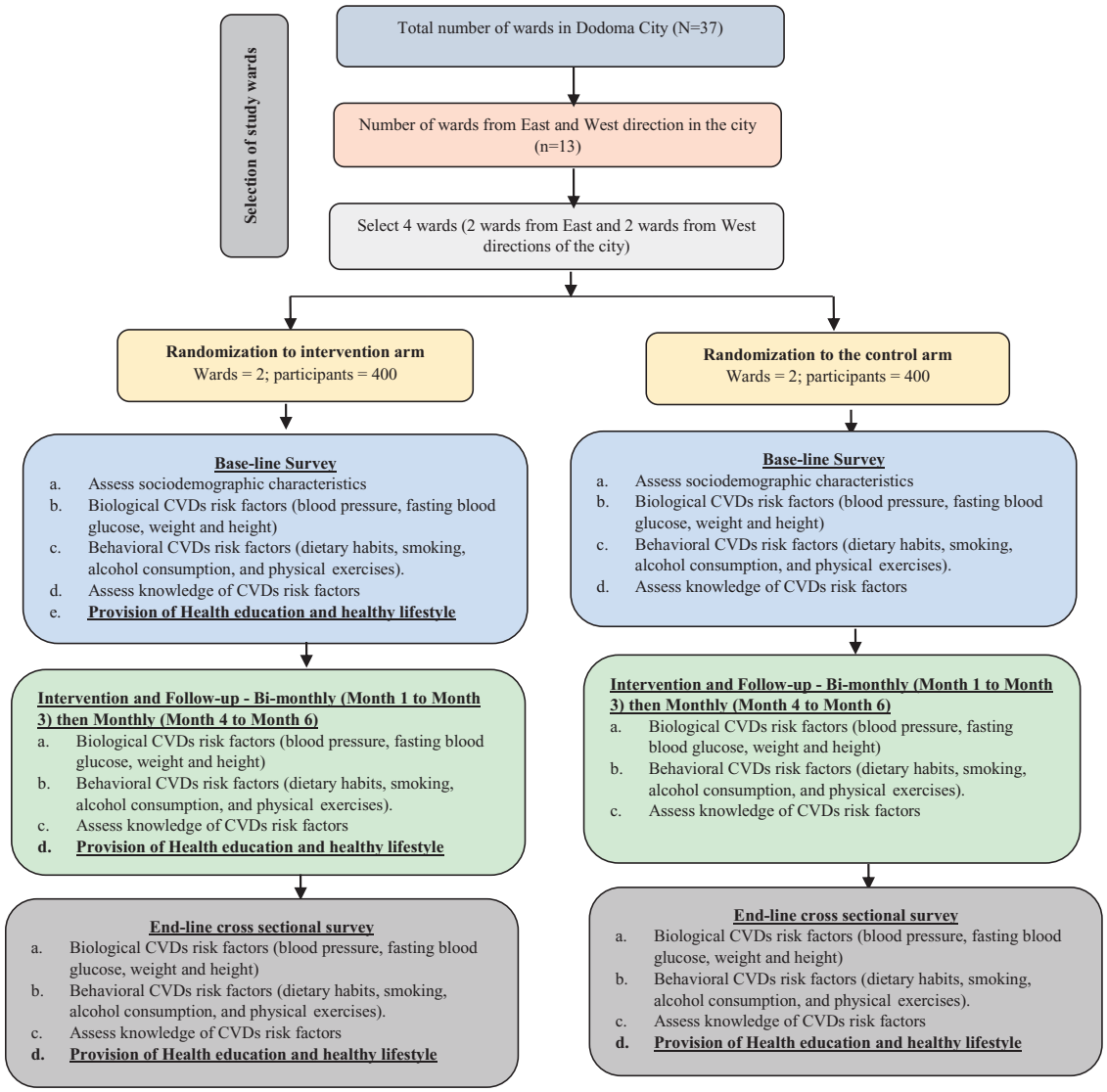

Figure 1: study design and flow chart

for the study. Lottery method will be used to select one participant at the household level.

Randomization and blinding

The unit of randomization will be the wards. The selected four wards will be grouped into two groups of two wards each, based on geographical distance between wards. The two groups will be randomly assigned to intervention and another two wards to control. This will ensure that intervention wards are bundled together but far away from control wards, hence minimizing contamination. A statistician who will not be the part of this study will do the final randomization of intervention and control wards. The flow of the study design is presented in Fig. 1.

Data collection tools and procedure

Baseline study

A cross-sectional survey will be conducted in four selected wards at the beginning of the study and after randomization. Researchers and trained research assistants will conduct face-to-face interviews in all selected wards using a structured questionnaire (Supplementary File S2). The questionnaire has been adapted from WHO-steps survey [29] and modified to meet the study objective. The questionnaire comprises the following parts: Part 1: Socio-demographic information. Part 2: Behavioral risk factors (dietary habits, smoking, alcohol consumption, and physical exercise) and biological risk factors (BMI, WC, blood pressure, and fasting blood glucose). Part 3: Effectiveness of community-based lifestyle education intervention on knowledge of CVDs risk factors. Part 4: Effectiveness of community-based lifestyle education intervention on dietary practices. Part 5: Physical measurements (blood pressure, blood sugar, weight, height, and WC). The data collectors will consist of the following qualifications: Laboratory technician who will be responsible for measuring blood glucose; registered nurse who will be measuring blood pressure; nutritionist will be responsible for measuring weight, height, and WC; and public health specialists will be conducting interviews. Health education and healthy lifestyle promotion will be delivered by a nutritionist, public health specialist, and a registered nurse.

Follow-up

Participants in the intervention and control groups will be followed up by researchers at home as follows: Twice monthly for the first 3 months, then monthly up to 6 months. During follow-up, participants in both arms will be measured blood pressure, blood glucose, weight, height, WC, physical exercises, smoking, alcohol intake, dietary habit, and their knowledge on CVDs risk factors will be assessed. Only participants in the intervention group will receive health education and healthy lifestyle promotion.

End-line study

End-line evaluation study will be conducted in both arms (intervention and control). Study variables (blood pressure, blood glucose, BMI, WC, dietary habits, smoking, alcohol consumption, and physical exercises and knowledge) assessed during baseline study will be re-assessed to measure the effectiveness of intervention. Knowledge on CVDs risk factors will be measured by using the same questionnaire used during the baseline survey.

Measurement of variables

Dependent variables

Dependent variables in this study will be BMI, WC, blood glucose, and blood pressure status [26–28].

Independent variables

The independent variables will be the healthy lifestyle education intervention that will consist of the followings: healthy eating practices, physical activities, reduction in excess alcohol drinking and cessation of cigarette smoking; and demographic characteristics.

Data processing and analysis

The data will be analyzed using SPSS version 21. Baseline characteristics of study participants in the intervention and control arms will be described through descriptive statistics (mean, SD, frequency, and percent). Inferential statistics will be used to compare the characteristics of participants, whereby independent *t*-test will be used to compare the characteristics between the groups (intervention and control) and paired *t*-test will be used to compare within the groups (baseline and end line). For all statistics, a two-sided *p*-value of ≤ 0.05 will be considered statistically significant.

Dissemination of results

The finding of this study will be presented and discussed at the University of Dodoma during academic symposium as well as at the department of public health before being submitted for publication in peer-reviewed journal for wider dissemination of the results. The finding of this intervention will be shared with relevant department at the Ministry of Health, Community Development, Gender, Elderly and Children for policy action in line with strengthening of primary prevention programs. Lastly, the results will be communicated to the community where this study will be conducted. The communication will be through dissemination meeting with Ward Health Committees and City Health Management Team.

Ethics approval and consent to participate

This study is approved by the University of Dodoma, Institutional Research Review committee (Ref. No. CB.299/308/2020). The Permission to conduct the study will be obtained from Regional Administrative Secretary of Dodoma, City Council Director, City Medical Officer, and local leaders from the selected wards. The details of the study will be explained to each study participants. The free informed consent written or verbal of each participant will be obtained before the study. Participants will have the absolute right and freedom to withdraw from the study at any time with no effect to them. Confidentiality and anonymity will be maintained by use of code numbers on the questionnaire rather than names. Participants found to have elevated blood pressure or blood glucose will be referred to their respective nearby health facilities for counseling, confirmation of diagnosis, and appropriate management.

Discussion

Given that the Tanzania strategic plan for reducing the burden of NCDs including CVDs has stressed on the shift from curative to preventive services [30], this strategy has not been implemented as efficiently as it could have been, especially in the area of primary prevention. This is due to the facts that Tanzania is still experiencing the rapid growth of modifiable risk factors that accelerate CVDs mortality and morbidity rates [31], which could be prevented through primary prevent. Primary prevention is an effective approach toward control of modifiable risk factors through a healthy lifestyle promotion intervention [32]. The main focus of this study is to develop and test an innovative community-based intervention aiming to reduce CVDs risk factors by promoting a healthy lifestyle among people vulnerable to develop CVDs risk factors. The intervention consists of delivery of health education and healthy lifestyle promotion for the prevention of CVDs risk factors. The study consists of two groups, the intervention and control. At the end, the study will compare the outcomes related to knowledge and prevalence of CVDs risk factors (biological and behavioral) in both groups. The aim is to provide evidence on the effectiveness of community-based interventions in improving knowledge and the reducing CVDs risk factors among vulnerable population in Dodoma City Tanzania. The primary prevention of CVDs through this kind of interventions is highly required in Tanzania which is facing a double burden of prevalence of communicable and NCDs, at the same time the country is faced by a shortage of both financial and human resources for the delivery of healthcare services [21]. The study setting will be urban community in Dodoma City, which is faced with rapid urbanization characterized by sedentary lifestyle (risk factor for hypertension, diabetes, and overweight) and raised cost for health care services which may hinder communities to seek services for early screening and treatment. Therefore, the selected study area is relevant for this kind of intervention in order to identify early those who are at high risk for developing CVDs, promote healthy lifestyle, and improve their knowledge for the reduction of CVDs risk factors in the community.

A major strength of this study is that, it attempts to assess the contribution of community-based lifestyle educational intervention toward reducing the risk of developing CVDs. Community interaction during the face-to-face education session and education materials that will be provided to each participant in the intervention group and the control group at the end of the study will create awareness, develop knowledge of CVDs risk factors, and how to prevent them. It is expected that this approach will be effective in identifying early those at risk for CVDs, and promote healthy lifestyle behavior which can

lead to the reduction of CVDs risk factors in the community and ultimately reduce premature deaths due to CVDs risk factors.

The limitations of this study include the following: the study population is characterized by diversity due to the expected inter-participant differences at baseline, regarding sociodemographic characteristics such as age and sex, biological CVDs risk indicators, and lifestyle behavior. This diversity can cause contamination of effects. These limitations will be minimized by using multi-level analysis with random effect models. The risk of contamination of the intervention will be minimized by grouping and randomizing, this means two close wards will be grouped to the same intervention arm and located far away from the two close wards for the control arm. Another expected limitation is on the diagnosis of hypertension using blood pressure readings taken on a single visit may overestimate the true prevalence of hypertension in the population. This limitation will be minimized by measuring blood pressure on every visit.

With this approach of testing the effectiveness of delivering CVDs risk factors prevention at community level we hope that, the findings of this intervention will influence the policy makers to design a sustainable and scalable intervention which enables communities to take control of their cardiovascular health, and therefore reduce mortality and morbidity related to CVDs risks factors.

Author contributions

N.S.G. conceived the study and will oversee implementation of the study, data collection, and analysis. N.S.G. and M.J.M. designed the study and prepared the first draft of the manuscript. S.K.N. revised the research questions and study design and reviewed the protocol. A.P.G. provided expert guidance to the design of the study and scientific review of the manuscript. M.J.M and S.K.N will supervise implementation of the study, data collection process, and participate in analysis. All authors read and approved the final version of the manuscript for submission.

Data availability

Not applicable because this is a protocol manuscript which contain no any data.

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Supplementary data

Supplementary data are available at *Biology Methods and Protocols* online.

Conflict of interest statement. None declared.

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