

Protocol

Effect of behaviour change communication on dietary diversity among women of reproductive age from different socio-demographic background (cluster randomized controlled trial): a study protocol

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ABSTRACT

Background: Low diet quality of women of reproductive age group (WRA) will have an impact on their health due to deficiency of important micronutrients. Indicator of assessing quality of the diet is minimum dietary diversity for women (MDD-W). With this background present research will be conducted with the objective to compare the dietary diversity among women of reproductive age group who received intervention with among women who did not receive any intervention.

Methods: Two-armed cluster randomized controlled trial will be conducted in urban slums and rural area of Pune district among women of reproductive age group. Estimated sample size will be of 325 participants in each arm. Data on dietary diversity will be collected and classified into ten food groups using 24-hour recall method. Behaviour change communication will be provided in two steps. Statistical analysis will be done using univariate and multivariate logistic regression, Chi-square test will be applied to test association between different socio- demographic variables and risk factors in the intervention and control arm.

Conclusions: The study will contribute to the existing literature on dietary diversity among women of the 15-49 years' age group of urban and rural parts of India, informing future research endeavors and policy initiatives.

Trial registration number: CTRI/2025/02/080693.

Keywords: BCC, Dietary diversity, Women of reproductive age group, Urban slums, Rural area

INTRODUCTION

To lead an active and healthy life human beings need a wide range of nutrients in the required amounts from the diet. The nutrients must be obtained by intake of combination of a variety of food items from different food groups. Women of reproductive age (WRA) mostly eat diets which are unbalanced and often monotonous and deficient in micronutrient.¹

Low quality of diet WRA group will have an impact on their health due to deficiency of important micronutrients. Thus it is essential to improve nutritional status of WRA.

The first step towards this is to understand their current nutritional status. One key indicator used to evaluate quality of the diet is minimum dietary diversity for women (MDD-W).² It indicates quality of diet and micronutrient adequacy. It indicates whether or not in the last 24 hours WRA have consumed minimum five food groups out of ten. Women with intake of minimum five food groups, are considered as having adequate dietary diversity and vice-versa.³

Inadequate dietary diversity among WRA can have serious health effect as it can affect their ability to conceive and can be an attribute for development of diseases like

coronary heart disease, hypertension, and diabetes.⁴ Considering this background, the present study will be conducted with the objective to compare the dietary diversity among women of reproductive age group who received intervention with dietary diversity among women who did not receive any intervention in Pune district.

Novelty

This study will be conducted among WRA from both urban and rural areas in Pune district, providing insight into the dietary diversity and food frequency patterns of women from different segments of the community. The intervention will involve behavioural change communication (BCC) and the demonstration of recipes using locally available food items, aiming to improve dietary diversity and overall nutrition.

Objectives

Primary objective is to assess and compare the changes in dietary diversity among women of reproductive age who received BCC interventions versus those who did not, after three-months of the final intervention.

Secondary objectives are to measure the effect of BCC on change in dietary diversity among WRA from different socio demographic background in Pune district, and to determine association between dietary diversity and nutritional status and sociodemographic factors among WRA.

METHODS

PICOTS

Population

Women between 15-49 years' age group who are permanent residents from the selected clusters.

Interventions

Step I includes BCC activities to promote dietary diversity, and step II included demonstration of healthy nutritious recipes from locally and seasonally available food items.

Comparison

No intervention (routine diet).

Outcome

Change in dietary diversity score.

Time

Three months after the step II intervention.

Research question

What is the change in dietary diversity score (O) of women of reproductive age group (P) who received interventions (I) to promote dietary diversity (O) compared to the WRA who did not receive any intervention (C) as assessed three months after the interventions (T)?

Study setting

Rural and urban field practice area of a Medical college in Pune district.

Study design

Community based two-armed cluster randomized controlled trial.

Study period

The duration of the study is from June 2025 to November 2026.

Exclusion criteria

Pregnant and lactating women from the selected clusters will be excluded.

Sample size estimation

The urban field practice area covers 33 Anganwadis and rural field practice area covers 29 Anganwadis. Each Anganwadi catering to a population of 1000 is considered as a single cluster. The WRA form about 25% of the total Anganwadi population. Hence on an average there will be about 250 eligible populations i.e. WRA in each cluster. A sample size of 271 in each arm will be required for the study to see change in dietary diversity score of 15% from baseline with 5% level of significance, with design effect of 1.249 and ICC of 0.001 to achieve 80% power. After considering 20% loss to follow-up, sample size will be inflated to 325 in each arm.⁵

Sampling techniques

Two stage cluster sampling was used. To get the required sample size, two clusters will be randomly selected from each urban and rural area and further randomized into intervention and comparison cluster. Interventions will be planned at the cluster level and all WRA in the clusters will be eligible to participate.

Study duration of total 18 months was divided as: baseline survey and enrolment (six months), and intervention (total six months): step I-three months and step II-three months; follow up (3 months) was conducted three months after step II intervention; and data analysis, interpretation and report writing (three months).

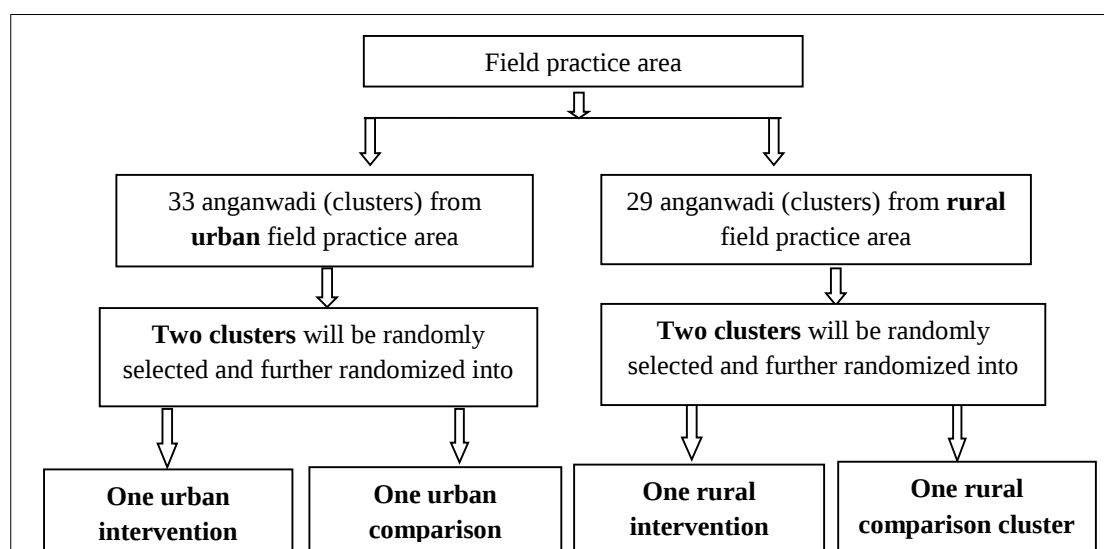


Figure 1: Field practice area.

Research tools

A total of six tools will be developed. They will be validated by external subject expert and pretested before its final use.

The tools are- focus group discussion (FGD) interview guide, in depth interview (IDI) semi structured interview schedule, and baseline/ enrolment tool will have following subheads.

Section A included socioeconomic and demographic profile, morbidity pattern, obstetrics history, section B included dietary diversity score assessment using 24-hour dietary history and access to different food sources, data on food insecurity, section C included anthropometric measurements: height, weight, waist and hip circumference, and section D included estimation of haemoglobin.

Intervention tool for step I

A pictorial booklet in Marathi language having following sections: information on balanced diet, nutritional health needs of WRA, recommended dietary allowance (RDA), various food groups; nutrient rich foods and their sources; nutrient deficiency disorders; and prevention and control of deficiencies.

Step II

Nutritious recipe booklet- locally available, seasonal, affordable, acceptable ten nutritious recipes will be covered and same will be demonstrated.

Follow-up tool

Having information pertaining to number of sessions attended, number of follow-up visits given, dietary

diversity score, anthropometric measurements and haemoglobin estimation (gm/dl).

Data collection methods

Qualitative study

FGD

FGDS of women of reproductive age group, ASHA workers, anganwadi workers and agricultural workers in the rural area (group of 6 to 8 women/FGD). FGDs will be conducted to understand their access to different food sources, local names of the food, cooking practices and understanding of food groups to create extensive food list for data collection. The number of FGD will depend on the saturation of the information.

IDI

8-10 interviews of community leaders, community health officers, medical officer PHC, ASHA supervisors to know food fads, food taboos, dietary patterns, seasonal availability of the food, challenges in achieving dietary diversity. Qualitative study will help in the refinement of research tool.

Quantitative survey

Baseline survey

Data will be collected by house-to-house survey. Information will be collected about socioeconomic and demographic profile of participants and dietary history by 24-hour recall method, their access to different food sources such as the cultivated food sources like farms and kitchen gardens and the built food environment like (village corner shops, local markets and the government's food security programs and food supplementation). Data

on food insecurity will also be collected. Data will be collected with the help of open-source software tool. Data on dietary diversity, anthropometric measurements and haemoglobin measurements of participants will be collected twice – during baseline survey, and three months after step II intervention.

Assessment of dietary diversity by 24-hour recall method

Data on all foods eaten by the participant will be collected by 24-hour recall method. Consumption patterns can be atypical during festive periods. So dietary data will not be collected during national holidays/celebrations or during periods such as Ramadan, Diwali, and Navratri. If more than one women present in the household, then younger woman in the house will be selected.⁶

The ten food groups are -grains, white roots and tubers, nuts and seeds, pulses, meat, poultry and fish, milk and milk products, green leafy vegetables, eggs, other vegetables, other vitamin A-rich vegetables and fruits, and other fruits. Dietary diversity will be considered adequate if the proportion of WRA achieves MDDS of five and above, whereas it will be considered inadequate if they consume less than five food groups.

Implementation of intervention

Step I

The BCC intervention will be administered to 8-10 WRA at a time, using a validated booklet. Interactive nutrition education sessions will be conducted in small groups till all the eligible WRA are covered in a period of three months. Information on 10 food groups will be given to the participants. Images of the food items from each food group will be shown to participants. The health benefits of intake of all 10 food groups, health effects caused by their deficiency, proper timing of having meals in a day and how to consume diverse diet from locally available food items will be explained. A fun quiz will be conducted in local language to evaluate understanding of the participants.

Step II

The second BCC activity will be imparted through the demonstration of healthy recipes from locally available food items for a group of 30 mothers. In addition, a recipe booklet will be prepared consisting of 10 easy to cook and from low cost locally available food items. This booklet will be distributed to the participants in the intervention area.

Nutritional assessment by anthropometric measurements

A calibrated electronic scale will be used to measure body weight of the participants and height will be measured by portable stadiometer. The minimum unit of measurement for height will be 0.5 cm and for weight will be 0.1 kg. Body mass index (BMI) will be calculated. According to

Asian-Pacific cut off points, BMI will be categorized. waist and hip circumference will be measured using standard techniques. Waist to hip ratio (WHR) will be calculated and cut off values for men and women will be considered as 0.88 and 0.81 respectively.

Assessment of anaemia

Haemoglobin estimation will be done by digital haemoglobinometer (Hemocue-Hb301). Based on the HB readings participants will be categorised using WHO classification.

Follow-up

During follow up 8/10 participants will be called in a group at a time. From all the participants' data on dietary diversity by 24-hour recall method, anthropometric measurements and haemoglobin estimation will be taken.

Table 1: History taking and anthropometric measurements at various stages of the study.

Stages	Dietary diversity score	Anthropometry	Hb estimation
Baseline	*	*	*
Intervention			
Follow-up	*	*	*

*Data to be collected

Quality check of the data

All the forms will be checked for completeness. Critical fields in the form will be identified and they will be monitored vigorously.

Expected outcome from the research

Expected outcomes include: improvement in DD score among WRA in the intervention arm, and increase in awareness about different food groups and improvement in nutritional status among WRA.

Plan of statistical analysis

Analysis of qualitative data

Qualitative data will be collected to understand the experiences of healthcare providers and community health workers in nutritional deficiencies, food fads, challenges in achieving dietary diversity as well as the perceptions of women. Field notes will be recorded and transcribed from FGDs and IDIs. We will use the MAXQDA software package for data management and analysis. Relevant text will be coded. Codes will be descriptive or analytical, and grouped into themes and sub-themes. A framework analysis will be used, primarily a case and theme-based analysis. Findings will be weighted by identifying key

themes and estimating the number of times they appeared and the number of respondents who mentioned them.

Analysis of quantitative data will be done using statistical package for the social sciences (SPSS) (version 29) and STATA software (version 15.1). Descriptive statistics will be considered for quantitative variables. Frequency and percentages will be considered for qualitative variables. To test association between different socio-demographic variables and risk factors in the control and intervention

arm Chi-square test will be applied. Univariate logistic regression will be applied to calculate benefit ratio (BR) of DD among intervention group. Adjusted benefit ratio (adj. BR) will be calculates of DD among intervention group by applying generalized linear model with family of binomial distribution and using link log function.

Throughout results 5% level of significance will be used, will also calculate 95% confidence limits.

Table 2 Timeline of the study.

Year	2024			2025								2026					
Activities	O c t	N o v	D e c	J a n	F e b	M a r	A p r	M a y	J u n	J u l	A u g	S e p	O c t	N o v	D e c	J a n	F e b
Pilot study, development and validation of research tool	X	X	X														
Enrolment of participants and collection of baseline data				X	X	X											
Interventions- step I, step II					X	X	X	X	X	X							
Follow-up data collection													X	X	X		
Data analysis , interpretation and report writing																X	X

Duration: 18 months

RESULTS

Study results will be drawn after conduction of the research in 2025-2026. We are expecting increase in the in MDD score and improvement in nutritional status of women of reproductive age group in the selected clusters of Pune district of India.

DISCUSSION

Present study will be implemented in the Pune district of Maharashtra, state in India. It is an important city in terms of its industrial and economic growth.¹⁰ Study conducted by Issa et al reported that 5.48 was the mean of dietary diversity and about 71.7% of WRA had an adequate minimum dietary diversity.³ In contrast to this other studies had shown low minimum dietary diversity.^{11,12}

According to NFHS 5 report in the Maharashtra almost 20.8% women in the reproductive age group has BMI below normal (BMI <18.5 kg/m²) and 54.2% non-pregnant women age 15-49 years are anaemic (<12.0 g/dl). In Pune district about 51.9% no -pregnant women of reproductive age group are anaemic, 19.6% women has BMI <18.5 kg/m².¹³ There is improved nutritional status among women and reduced risk of anaemia and adverse pregnancy outcomes and by adaptation of diverse diets.¹⁴

In the present study behaviour change intervention will lead to improvement in knowledge about dietary diversity which will help WRA to take better care during vulnerable periods of life namely pregnancy, and lactation.

Strength and limitations

Many prior studies had been conducted either in the urban slums or in the rural area. This study will be conducted both in urban slums and rural area hence researchers will come to know the dietary diversity and nutritional status of women of reproductive age group from different areas of the community simultaneously.

The study will be conducted in selected clusters from rural area and urban slums of Pune City. Hence this may affect. the generalizability of the findings women of reproductive age group from other rural area and urban slums.

Future research studies should include larger samples to generalize the study findings.

CONCLUSION

This study aims to assess dietary diversity among women of reproductive age group of urban slums and rural area. Dissemination of the study findings will help in designing tailored intervention program of nutrition for the women of reproductive age group which ultimately leads to improved nutritional status among them.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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