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Usefulness And Effectiveness Of Locally Available Food That Can Improve Gut Flora Using Mhealth Among Malnourished Nomadic Tribe Children Of Sikar, Rajasthan: Protocol For A Randomized Control Trial

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Abstract:

Background

Gut microbes help in the absorption of nutrients in food, and poor gut health can impact the growth and development of children. In addition, poverty and poor sanitation practices enable high rates of enteric infections. As a result, diarrhea remains unabated in the lower economy sections. Mothers' awareness regarding the gut health issues of their children via mHeatlh (mobile audio messages) can be one of the many ways to strengthen gut health issues among children.

Objective

The study objective is to design, develop and evaluate mHealth intervention to improve gut health among the tribal community of Sikar district of Rajasthan through a randomized control trial.

Methods

A randomized control trial study will be conducted with 300 participants from nomadic tribes (Banjara, Luharu, Sapera) of Sikar, Rajasthan. Eligible participants include mothers of 6 months to 5 years old malnourished children, those who agreed to participate in the study, are available for follow-up interviews, and have at least a basic phone. The malnutrition status of the children will be determined via WHO Z-Score. The mothers of the participant children will be randomized into the following two groups: the intervention group (pre-recorded mobile-based audio messages) and the control group (paper-based one-time message booklet). Study participants in the intervention group will receive a daily automated system-generated recorded message via phone call. Control group participants will be provided with

a paper-based booklet. Follow-up visits will be conducted at 3 and 6 months from the baseline in both groups. Differences in diarrheal episodes, knowledge, attitudes, and practices of mothers will be measured across the groups.

Results
Descriptive analysis of the gathered data will be performed using SAS v9.1. Results will be reported at 95% CI and $P<0.05$. The proposed research study will help to explore the possible mHealth acceptance and its further use to improve health in the nomadic tribe population.

Conclusions
The finding from this research project will aid in developing and implementing data-driven, evidence-based mHealth audio intervention to address gut health issues in malnourished children.
The study will provide insights into the barriers and challenges leading to poor gut health of the children in nomadic tribe populations and the relationship between gut health and other environmental factors in the children.

Keywords: Child gut health; Child Malnutrition; mHealth; Nomadic tribe; Audio-based intervention

Introduction:

Gut health is important to a child's physical growth and development. Malnourished children have defects in the development of their gut microbiota [1] hence they are more prone to gut health issues like diarrhea, bloating, constipation, etc. The food is intercepted by trillions of microbes [2]; these microbes help maintain good gut health. India is still a lower-middle-income country even though it has the fastest-growing economy in the world [3]. The fact that children who live in lower-income families have disproportionately food insecurity and malnourishment is an unacceptable reality [4]. . A previous study from India identified changes in the gut microbiota of children of varying nutritional status, including stunting [5]. Malnutrition in children is part of a vicious cycle of recurrent infection, poor immunity, and poor handling of malnutrition, compounded by food insecurity [6]. Recently, alteration in the gut microbiome has been recognized as part of this vicious cycle [7] because the gut microbiome plays a crucial role in nutrient assimilation and harvesting the energy from food. As a result, dysbiosis of the gut microbiota has been implicated in undernutrition [8]. Diet plays a vital role in the gut microbiota composition and its function [9]. Few indigestible food components (such as fiber) are broken down by commensal microbiota in the gut [4]. Direct and indirect dietary intakes (from the maternal diet during pregnancy and lactation to consumption by infants) [10] are thought to be a significant drivers of the gut composition of the infant. Breast milk and formula milk have differences in the composition of the gut microbiota; for example, breastfed infants tend to have lower bacterial diversity and a higher relative abundance of beneficial Bifidobacterium species than formula-fed infants [11]. Poverty and poor sanitation practices enable high rates of enteric infections. As a result,

diarrhea remains unabated in the slum. Although oral rehydration therapy (ORS) has greatly reduced diarrhea-associated child mortality, poor intestinal absorption and enteric infections persist and affect 50 percent of children worldwide and 30 percent of children in developing countries, resulting in up to 43% stunted growth [4].

Rajasthan is the north-western part of India and is the most extensive state in terms of area. This state has varying topographic features, and the parched region dominates a significant part of Rajasthan. Lack of green vegetables, inadequate water, and other factors associated with the climate, Rajasthani food developed its food habits to suit the climatic conditions. Pearl millet is the staple crop of Rajasthan. Also, it is home to many nomadic tribal populations (13.48 % of the total Rajasthan population) [12]. Usually, they live in forests or hills; if they are in a city or village, they settle their colonies a little away from the other communities. In addition, such communities typically refrain from the help of modern health [12].

Why "mHealth-Audio-based intervention" to deliver messages?

Mobile "health can be accessible, affordable, and sustainable for such a population. However, despite higher mobile phone usage by the Indian population, tribal people are not free from limitations. Although the study shows that tribal people started reaping the benefits of telecommunications, they also spent money on mobile phone recharge. Other studies also showed that mHealth strategies could improve the maternal, newborn, and child health (MNCH) services in the tribal population [13,14]. Health education through technology, particularly mHealth (mobile health), is an impactful medium for increasing patient education [15]. The global observatory for electronic health defined mHealth as healthcare-related practice assisted by mobile devices [16].

Need for the study

mHealth is a powerful tool to improve the participants' knowledge concerning the condition and disease; it also helps manage and prevent illness and disorders. Hence, this study aims to examine the usefulness and effectiveness of mHealth Audio-based Intervention for Malnourished Children (AIM-Children) in improving gut health among malnourished nomadic tribe children of Sikar, Rajasthan. The study will further explore the association between poor water and sanitation practices; dietary habits; knowledge, attitude, and practices of the mother, and their influence on the children's gut health.

Study Objective

The study's objective is to design, develop and evaluate mHealth intervention to improve gut health among the tribal community of Sikar district of Rajasthan through a randomized control trial. To the best of our knowledge, this is the first study to design and develop a mobile phone-linked intervention model using a participatory-based approach among users from nomadic tribe settings in an Indian context.

The proposed study has three objectives:

1. Examine the factors that influence gut health in children of the nomadic tribe community.
2. Identify the necessary components of the mHealth (AIM-Children) platform that can deliver audio messages to the participants.
3. Compare the effectiveness of the AIM-Children mHealth intervention to the paper-based methods of delivering health information among participants.

Methods

Study Design and Population

Study participants will be recruited from nomadic tribe populations: *Banjara, Luharu, and Sapera* communities of Sikar district of Rajasthan. A study plan to recruit a total of 300 mothers of malnourished children using a nonprobability complete enumeration sampling method. The study participants will be randomized into two groups: Intervention (mobile linked audio messages); and Control group (paper-based health information).

Differences in the dietary pattern, mother's WASH-related knowledge, attitudes, and practices will be measured across groups.

Inclusion criteria
a) Parent of the child (age 6 months to <5 years)
b) Malnourished Children: Malnutrition status will be determined based on the WHO nutrition status guidelines [17]
c) Parents of children agreeing to participate in the study
d) Available for a follow-up interview
e) Residing in the nomadic tribe dwelling
f) Have a mobile phone

The exclusion criteria comprised of the following:
a) Presence of any mental or physical challenges in children
b) Unavailability of participants for telephonic follow up
c) Involvement in other trials or protocols related to dietary assessment

Data Availability:

The data supporting this study's findings are available on request from the corresponding author upon reasonable request.

Proposed Intervention AIM-Children: A mobile- Audio-based Intervention for Malnourished Children (AIM-Children) will be designed to provide health education in relation to gut health to the mother of malnourished children suffering from frequent diarrhea episodes. A human-centered approach will be utilized in the design process. The principle of a Human-Centered Design (HCD) requires that the end-user be prioritized in the intervention design. HCD is used to design novel health care products and programs. It is a series of methods that allows researchers to study a product user's needs and other factors like environment and then design accordingly [18–20]. HCD enables the researcher to alternate

between divergent and convergent thinking, broadly analyze the context and possible solutions, and converge that as an end product with the problem statement, approach, or solution [21]. Audio messages will be of a duration of 30-60 seconds. The platform will also generate the call details report, listening time, and miss calls.

The system <u>AIM-Children</u> is comprised of the following components.
1. Daily automated call
2. Maintain call records electronically

The audio database will include the following components:
1. Food choices
2. Nutritional information
3. WASH practices
4. Knowledge related to WASH
5. Use of locally available food to improve gut health
6. Government policies to manage child health
7. Home remedies to improve gut health

The audio message library will be prepared in Hindi (a local, regional dialect). In addition, WASH practice knowledge will be provided based on the study participants (mothers of malnourished enrolled children). To ensure efficiency
a) Weekly check on the data
b) Team meeting with local mascots weekly
c) Weekly follow-up for the data understanding with data management personnel.

Variable Assessment

- *Sociodemographic Profile:* Baseline data will be gathered on both mother and child socio-demographics such as the age of the mother, education, child's age, family, household income, household employment status, education level, and ethnicity.
- *Food Insecurity:* Food Insecurity Experience Scale Survey Module (FIES) will collect data on food insecurity. It is developed by the Food and Agriculture Organization (FAO). This scale is an experience-based measure and has been validated for cross-cultural use to access pointers of food security. It consists of eight short questions with dichotomous (yes/no) responses. The scale also seeks data on degrees of food security in the pre-post covid-19 [22].
- *Water and Sanitation Hygiene Practice (WASH):* Practices on handwashing and sanitary habits will be gathered [23].
- *WHO Z-score:* A Z score will be measured to determine the nutrition status of the children. Children with moderately malnourished will be included in the study. [12]
- *Anthropometry:* Height, weight, and waist-hip circumference will be measured using a standard technique.
- *Knowledge Attitude Practices:* This data gathers participants' WASH, Food pattern knowledge levels, and attitudes and practices towards preventive practices to minimize

gut health issues. The information recorded would help design targeted public health messaging to address KAP related to the children's gut health [24].

- *Child gut health status:* A questionnaire on child health status will be gathered with the help of the caretaker of the child. Data will be collected on diarrheal frequency, type of stool, and child food habits [24].
- *Client Satisfaction Score-CSQ-8:* This will be measured using the Client Satisfaction Questionnaire (CSQ8). The CSQ8 is an 8-item questionnaire rated using a 4-point Likert scale [25].

Informed Consent

Ethical approval was obtained from the UREC (University Research Ethics Committee) of DIT University, Dehradun, Uttarakhand, India (DITU/UREC/2021/07/6). The researcher will describe the study in Hindi dialect, the time required, the benefits of the survey, and the results to the mother of enrolled children. Those willing to participate and provide their consent will be enrolled in the study. The researcher will explain the consent to the participant in the local Indian dialects. Ethical consent will be obtained with the help of a legally acceptable representative or impartial witness [26]. A signature or thumbprint on the local dialect Hindi consent form will be taken. Study participants will be allowed to withdraw/from the study without mentioning the reason for withdrawal. All data, including those from study withdrawals, will be reported for final analysis. The mid-withdrawal data will be separated from the final result of the study. Each participant's data will be taken care of confidentially, the time of the respondent will be respected, and their voluntary participation will be appreciated. Non-monetary forms of compensation can be given to avoid coercion and undue inducement, which can impact the result of the study [18]. The UREC-approved consent form will be administered to the eligible individual describing the study, the measure used by the researcher to protect the confidentiality of the respondents, and the volunteer nature of the study. The researcher will obtain the signature of the participants and will sign the consent form themselves; and one copy will be provided to the study participants, and one copy will be retained by the researcher.

Data Collection, Data Entry, and Quality Assurance

With the local mascot's help, the researcher will collect the data, and data entry will be done by the researcher only. The researcher of the study will be responsible for the data management tool. The data will be collected for the focus group, baseline, timeline 1 (after one month of the baseline), and timeline 2 (after one month of timeline 1). The data for the focus group will be collected on paper and recorded electronically too. The transcription of data will be done and entered into the researcher's Microsoft Excel (Microsoft Corporation) sheet.

Expected Outcomes

The study outcome includes the improvement in gut health and the episode/frequency of diarrhea in the intervention group. The researcher will also explore the change in WASH knowledge, attitude, and practice of the mother across the setting.

Data Analysis Plan

The data will be gathered and presented in tables comprising the recorded characteristics of complete variables. These tables will fulfill the purpose of data quality control to correct the data pattern in terms of inconsistencies, outliers, or missing data. Descriptive analysis will be conducted to report the means and SDs of the continuous variable and frequency analysis for the categorical variables. T-tests will be performed to compare the means between the constant variable, and chi-square will be performed on categorical variables. Finally, the comparative analysis will be performed to determine the predictors of the outcome variables of the mHealth intervention in the context of the gut health of the child and the KAP of the mother. All research will be conducted on SPSS v27, and the results will be reported at 95% Cis and P=0.05.

Project Timeline and Milestones

Data will be collected at baseline with follow-up conducted each month 1, 2 results in 3 data collection time points. After each time point, a follow-up intervention will be scheduled to administer the study questionnaire.

Implementation of the Intervention

The study participants will be assigned randomly into two groups. Intervention (mobile linked audio messages); and control group (paper-based health education/booklet). The randomization will be conducted following the agreement on children's eligibility for inclusion in the study. Both groups will be provided with booklets at baseline follow-up. In addition, visits will be conducted in month 1,2 from the baseline. In both groups, baseline data will be gathered on socio-demographics, KAP (knowledge attitude practices) of mother, child's sleep pattern, anthropometric measurement, eating habit, stools frequency, and type of children diarrheal episodes, and follow-up data will be gathered at the end of the intervention to compare the differences.

A detailed study timeline is presented in Table 1.

Table 1. Project Timeline and Milestones

Month / Task Involved	1	2	3	4	5	6	7	8	9	10	11	12
Review of the literature, initial designing, and planning of the study	✓											
Development of study proposal and ethical approval	✓											
Approval of the study proposal	✓											
Development of survey items and the questionnaire	✓											
Review and revision of the questionnaire by the research		✓										

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	1	2	3	4	5	6	7	8	9	10	11	12	13
team	▓												
Training of the local mascot team	✓												
Focus group discussion		✓	✓										
Initial data analysis, results write up, and dissemination of the focus group					✓	✓							
Revision of the questionnaire based on the focus group			✓										
Recruitment of the target sample and baseline data collection				✓	✓								
Timeline 1						✓	✓						
Timeline 2							✓	✓	✓				
Results write-up and preparation of the manuscript									✓	✓	✓	✓	✓
Dissemination									✓	✓	✓	✓	✓

Ethics and Dissemination

The study bears UREC (University Research Ethics Committee) of DIT University, Dehradun, Uttarakhand, India Reference No. DITU/UREC/2021/07/6 in July 2021. The study will be conducted under the supervision of supervisors. The complete finding of the study will be disseminated through peer-reviewed publications. Also, the result will be presented at national and international conferences. In addition, the finding of the study will also be disseminated to the local community, mascots, and institutes.

Results

The proposed research study will help to explore the mHealth possibilities and its impact on health in the nomadic tribe community. The proposed research study will also help explore the role of preventive measures (WASH practices) and locally available food in improving gut health among malnourished children of nomadic tribes. We anticipate that the intervention group will show a significant change in improvement in gut health, dietary pattern, WASH practices, knowledge, attitude, and practice of the mother. The study's results will help design and develop a user-centered informatics platform that can deliver multimedia-driven nutrition and health educational modules tailored to facilitate healthy habits and improvement in gut health in children of tribal settings. The focus group study has been conducted, and baseline data from 300 study participants in both the intervention (n=150) and control groups (n=150) has been completed. Follow-up data collection for months 1 and 2 is ongoing. We expect the follow-up data collection to be completed by

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December 2022. We are currently analyzing the focus group data and generating reports, which will be presented in our upcoming manuscript.

Discussion

The study would help in assessing the rates of mhealth acceptance and its determinant among the nomadic tribe community of Sikar, Rajasthan. The proposed project finding would help identify, develop, and implement data-driven, evidence-based behaviour modification interventions to address the gut health issues among children of nomadic tribe localities. The study will provide insights into the barriers and challenges leading to poor gut health and the relationship between gut health and other environmental factors in children. There is an immense need for strategies to increase the knowledge, attitude, and practices related to WASH of the mother while being sensitive to religious or philosophical beliefs. We also anticipate that satisfaction with care (Client Satisfaction Score-CSQ-8) will be significantly higher in the intervention group, owing to the unique features: listening to the audio and time of the listening audio. A previous study reveals that the impact of mHealth interventions in low-income household women in India showed statistically significant differences in several infant care practices and the effect on knowledge and behaviors shown to improve infant health outcomes [27]. Audio-based Intervention for Malnourished Children (AIM-Children) will be the first of its kind to be implemented in the nomadic tribe setting of Rajasthan, with the potential to create awareness related to gut health and nutrition management of children in a broader scope. The uniqueness of AIM-Children is demonstrated through its cultural and contextually relevant features: allowing audio delivery in local dialect Hindi, enabling conversation with the participant weekly, sustained data collection, and participant adherence through call-linked care. We conducted focus groups with the study population in addition to literature reviews to identify user characteristics, knowledge, attitude, practice, needs, and preferences that potentially influence users' satisfaction with the mHealth intervention [27].

Study Contributions and Implications

All the respected authors have contributed to the study's design, development of the tools, and manuscript preparation and have been approved for publication.

Strengths and Limitations

The study would provide an in-depth understanding of various factors related to poor gut health among malnutrition children in the Indian nomadic tribe setting. The study is being only conducted on the nomadic tribe population of the Sikar district of Rajasthan; another tribal dietary pattern may vary. The study results may be utilized to formulate the appropriate intervention feeding program nationally. However, further research involving extended follow-up is needed to explore the impact of such intervention on the long-term outcomes.

Acknowledgments

Abbreviations

WASH: Water and Sanitation Hygiene Practice
FIES: Food Insecurity Experience Scale Survey Module
FAO: Food and Agriculture Organization
KAP: Knowledge Attitude Practice
CSQ: Client Satisfaction Score

Conflicts of Interest: The authors declare no conflict of interest regarding this manuscript.

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