

HEAL (Healthy Eating and Active Living): To improve health and well-being of individuals by addressing social, economic and health inequities: Protocol for a cohort study

Ashish Joshi, Surapaneni Krishna Mohan, Apurva Kumar Pandya, Ashoo Grover, Harpreet Kaur, Mansi Gupta, Heemanshu Aurora, Ashruti Bhatt

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Abstract

Background: Health inequity is interlinked with good health and well-being of an individual. Digital health interventions have the potential to reduce the existing health inequities.

Objective: The study aims to identify determinants of social, economic, and health inequity in diverse settings to enhance Healthy Eating and Active Living. It further aims to design and develop a digital health intervention HEAL (Healthy Eating Active Living) incorporating framework of human centred design to enhance Healthy Eating and Active Living among rural and urban population groups of Chennai, Tamil Nadu.

Methods: A prospective, 3-year cohort study will be conducted. The study aims to recruit 6350 individuals across rural and urban settings of Chennai, Tamil Nadu. A total of eleven sites have been selected for participation in the study. Data will be gathered for sociodemographic, economic inequity, HEAL profile, depression, anxiety and stress, well-being, sources of health information, perceived access to health care, health literacy, navigation of health literacy, satisfaction with health system.

Results: The study would help to explore the determinants of social, economic and health inequity across multiple sites. Data analysis will be performed using SAS v9.3 and results will be reported as 95% CI and p-values. The findings of the study will inform the design and development of a tailored, interactive human centered digital intervention to enhance the health and well-being of the population groups of Chennai.

Conclusions: The proposed study will help in examining the role of the proposed HEAL intervention to enhance the good health and well-being of the population groups of Chennai.

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Original Manuscript

HEAL (Healthy Eating and Active Living): To improve health and well-being of individuals by addressing social, economic and health inequities: Protocol for a cohort study

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Abstract

Background: Health inequity is interlinked with good health and well-being of an individual. Health inequity can be due to various socioeconomic factors like income levels or social status. Digital health interventions have the potential to reduce the existing health inequities.

Objective: The study aims to identify determinants of social, economic, and health inequity in diverse settings to enhance Healthy Eating and Active Living. It further aims to design and develop a digital health intervention HEAL (Healthy Eating Active Living) that incorporates a human-centered design framework in order to improve Healthy Eating and Active Living among rural and urban population groups in Chennai, Tamil Nadu.

Methods: A prospective, 3-year cohort study will be conducted. The study aims to recruit 6350 individuals across rural and urban settings of Chennai, Tamil Nadu. A total of eleven sites have been selected for participation in the study. Data will be gathered for sociodemographic, economic inequity, HEAL profile, depression, anxiety and stress, well-being, sources of health information, perceived access to health care, health literacy, navigation of health literacy, and satisfaction with health system.

Results: The study would help to explore the determinants of social, economic and health inequity across multiple sites. SAS v9.3 will be used for data analysis, and results will be reported as 95% CI and p-values. The study's findings will guide the design and development of a tailored, interactive human-centered digital health intervention to enhance the health and well-being of Chennai's population groups.

Conclusions: The proposed study will help in examining the role of the proposed HEAL intervention to enhance the health and well-being of the population groups of Chennai.

Keywords: Health inequity, health, well-being, digital interventions

Introduction

Background and rationale

The World Health Organization (WHO) identifies health inequities as “systematic differences in the health status of different population groups” [1]. Further, WHO refers to Health as “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity” [2]. Consequently, research on health inequity is a central agenda component of the 2030 Sustainable Development Goals (SDGs) and various government and development dialogues[3] ,[4]. Despite this, WHO reports that, health inequalities exist at varying degrees around the world, both within and between countries [5]. These inequalities further exacerbate health disparities between rich and poor, urban and rural, employed and unemployed populations and between low-, middle-, and high countries [6 due to socioeconomic factors such as social status or income levels etc [7].

According to the Centers for Disease Control and Prevention (CDC), health equity can be attained when every individual can “attain his or her full health potential” and no one is “disadvantaged from achieving this potential because of social position or other socially determined circumstances” [8]. This also emphasizes the significance of measuring health inequity, to promote opportunities and to monitor the progress in health and intersectoral strategies. Additionally, measuring the interrelationship between health and its social determinants is vital to promote effective interventions for health equity [9].

Inequalities are unfair, affect everyone, and are avoidable, however, the underlying factors causing inequality are imperfectly understood along with limited evidence on effectiveness of interventions to reduce inequalities is limited [12]. Prior research has further highlighted the issue of good health for socio-economically vulnerable groups, and the need for targeted public health interventions in India [13]. A study indicated that health inequity in India is pro-rich and that despite services being available to people there was a lack of awareness around it especially in the rural region [14]. Considering the diversity in India, and the prevalent social inequalities, the literature also emphasises on the importance of research in health inequalities for monitoring the health policies and programs [13].

Equity was also identified as one of the key principles of the India’s 2017 National Health Policy [10]. However, with limited evidence base of health equity in India, it is required to generate empirical data for the variables that create, sustain, and reinforce inequity. This would further help the policy makers to prioritise and strategize the limited resources available for the health system of the country [11].

However, the paucity of data for health inequalities in India and the subsequent research gap on critical issues related to health inequity of the country also underscores the probable impact of policies and strategies deployed to enhance the well-being of population groups. Moreover, the COVID-19 pandemic has exacerbated the health inequity worldwide [15]. Also, eating habits is possibly determined by the socio-economic status of the individuals [16]. Thus, the present study aims to enrich the current understanding on health inequity with empirical research. The findings will also help with the design and development of digital health intervention HEAL (Healthy Eating Active Living) to improve the good health and well-being of individuals by addressing social, economic and health inequities. Tamil Nadu was the chosen region of study as it seems to be state that has progressed in health care in the recent years hence the study aims to see the receptivity to digital intervention of the study population in these settings [14].

Study Objectives:

- To identify determinants of social, economic, health inequity to enhance healthy eating and

active living among rural and urban population groups of Chennai, Tamil Nadu.

- To design and develop a digital health intervention HEAL using SMAART model targeted to enhance healthy eating and active living among rural and urban population groups of Chennai, Tamil Nadu.
- To evaluate impact of the proposed intervention to address burden of social, economic and health inequity to enhance healthy eating and active living among rural and urban population groups of Chennai, Tamil Nadu.

Methods

Study Overview

The proposed research involves multidisciplinary team in Population Health, Epidemiology, Socio-behavioral sciences, Anthropology, and Biochemical Sciences.

Study design and population

The HEAL cohort study is a prospective, 3-year cohort study with the aim to recruit 6350 individuals across rural and urban settings of Chennai, Tamil Nadu. The study sample will be recruited from Kannur, Pannur, Thirumenikuppam, Thodukadu, Kottaiyur, Nemili, Mannur, Kiloy, Ulundai, Narasamangalam, Karanai, Panimalar Medical College Hospital and Research Institute (PMCHRI) and Rural Training Health Centre (RTHC) Chennai and Maligaipaddu village of Chennai, Tamil Nadu. Baseline evaluation will be performed at the time of recruitment of study participants. The study participants will be recruited through convenience sampling. This will serve as cross-sectional data to estimate the prevalence of determinants of social, economic and health inequity.

Study intervention

HEAL intervention will be designed based on the SMAART model to enhance the healthy eating and active living for the individuals participating in the study. This intervention will ensure coordination of social, economic and health related parameters to enhance the health and well-being status of the population. The SMAART (Sustainable, Multi-Sector, Accessible, Affordable, Reimbursable, Tailored) model works on the principles of Data, Information and Knowledge (DIK), Human Centred Approach, Information Processing Theory, and humanistic, behavioural, and learning theories [17]. The intervention stage will have two parallel groups (case and control) for comparison. Individuals in the intervention group will be provided access to the informatics-based intervention for enhancing their healthy eating and active living. The participants from the intervention stage will be included in the study based on participants from the baseline stage consenting to participate in the intervention. The participants will be assigned to the intervention or control group through randomisation. They would be provided information on good dietary habits and importance of regular physical exercise for maintaining good health and well-being. Individuals in the control group will be provided educational booklet as standard care. The intervention will be a tailored multilingual digital health intervention. Both the groups will undergo a series of baseline and follow up assessment for estimation of change in eating pattern, physical activity and well-being to assess the impact of intervention.

Study location: Both urban and rural areas of selected sites

Study duration: 3 years

Study population: All older adults aged 18 years and above

Inclusion criteria:

- Individuals aged 18 years and above.
- Individuals from both urban and rural areas.
- Individuals with consent to participate in the study.

Efforts will be made to include individuals of varied age groups, gender, location and socio-economic status.

Exclusion criteria:

- Individuals below the age of 18 years.
- Individuals who would not give their consent.
- Individuals who have impaired cognition

Informed consent

The institutional review board–approved informed consent form will be administered by the research team to the eligible individuals for the study. The research team will describe the study, time required, and benefits of the study results to the participants, and those willing to participate and give their consent will be enrolled in the study. Written informed consent will be obtained in both English and local Indian dialects at time of data collection if the participants are able to read and understand the questionnaire. In case of uneducated participants audio recording of the consent will be done. Study participants will be allowed to withdraw from the study at any time [18].

Data Collection, Data Entry, and Quality Assurance

Data collection and data entry will be performed by a team of trained field data collectors and data management. Data will be gathered in the field on paper and then entered on the computer. The data will be entered in the computer using Microsoft Excel. For quality assurance, a clearly defined data collection and management protocol will be in place. This will include a well-defined study manual with all the relevant instructions. For quality assurance we will have a trained team of data collectors, weekly meetings with the research team, weekly data checks, maintenance of study participant contact, and maintenance of study participant data instrument logs.

Data Security and Privacy

Data security will be ensured through regular backups in password-protected computers in a locked office of the principal investigator. Data will be stored for 5 years from the point of study completion after which it will be destroyed. All the physical data files will be stored in a locked file cabinet in the office. The information will be accessible to members of the research team only.

Variable assessment

1. *Socio-Demographic*: Information will be collected on participants age, gender, educational status, migration status, disability status, occupation, household size, family size, income, and number of earning members in the household.

2. *Economic inequity*: Wealth index is division of households into 5 wealth quintiles to show relationship between wealth, population, and health indicators [19].
3. *HEAL Profile*: Data will be collected on the respondent's health and lifestyle profile. We will utilize the WHO STEP wise Approach to Non-Communicable Diseases (NCDs) Risk Factor Surveillance (STEPS) questionnaire. It is a simple, standardized method for collecting, analysing, and disseminating data on key NCD risk factors in countries. The survey instrument covers key behavioral risk factors: tobacco use, alcohol use, physical inactivity, unhealthy diet, as well as key biological risk factors: overweight and obesity, raised blood pressure, raised blood glucose etc [20].
4. *Depression, Anxiety and Stress*: Data will be gathered from the respondents about their mental and well-being. We will utilize the Depression, Anxiety, and Stress Scale (DASS). The DASS is a set of three self-report scales designed to measure the negative emotional states of depression, anxiety, and stress. Each of the three DASS scales contains 14 items, divided into subscales of 2-5 items with similar content [21].
5. *Well-being*: The Short Warwick Edinburgh Mental Well-Being Scale (SWEMWBS) is a shortened version of the Warwick-Edinburgh Mental Well-Being Scale (WEMWBS). It measures both mental and emotional well-being (how "good" somebody feels) and psychological functioning (how well somebody thinks they are functioning). This scale is suitable for ages 13-74 years and works well as a "before" and "after" tool to measure change in well-being during an intervention or specific program[22].
6. *Sources of health information, social media, technology access and familiarity*: Information will be gathered about cell-phone ownership in households, type of cell phone, access to internet, and knowledge of text messaging [23] [24].
7. *Perceived access to health care*: Information will be collected from the respondents regarding the access to healthcare. We will utilize Perceived access to health care questionnaires. The questionnaire includes six dimensions: 1) availability, 2) accessibility, 3) affordability, 4) accommodation, 5) acceptability, and 6) awareness. In addition, the psychometric evaluation was conducted on the instrument's initial version with 31 items on a 5-point Likert scale (strongly agree to strongly disagree) [25].
8. *Health Literacy*: REALM will be utilized to assess the health literacy of the study participants. It is a quick screening tool to assist physicians in identifying patients with limited reading skills and in estimating patient reading levels. 'At risk patients' are defined as those with a score of six or less [26].
9. *Satisfaction with health system*: The Patient Satisfaction Questionnaire (PSQ-18) yields separate scores for each of seven different subscales: general satisfaction (2 items), technical quality (4 items), interpersonal manner (2 items), communication (2 items), financial aspects (2 items), time spent with doctor (2 items) and accessibility and convenience (4 items) this questionnaire will be employed both at baseline and post intervention [27][28].

Outcomes

The study outcomes include identification of determinants of social, economic, and health inequity. The research would further help in identifying the key areas which need to be addressed through intervention to improve the health and well-being status of the general population. Additionally, the study would also help in developing tailored intervention targeted to reduce the social, economic, and health inequities.

Data analysis

Descriptive analysis will be conducted to report mean and standard deviation of the continuous

variables and frequency analysis on the categorical variables. T test will be performed to compare means between the continuous variables and a categorical dependent variable while chi-square analysis will be performed for the categorical variables. Multivariate regression analysis will be performed to determine the determinants of social, economic and health inequity. All analysis will be performed using SAS v9.1 and reporting of the results will be done at 95% CI and $p < 0.05$.

Projected timelines and milestones

A detailed research plan and scheduled timeline of the tasks involved in the study are presented in Table1.

Table1: Scheduled timeline of the tasks in HEAL Study

Variables	h 1	hs 2-5	hs 6-7	hs 8-10	hs 11-18	hs 14- 30	hs 31-33	months 34-36
Stakeholder meeting	X							
Baseline Data collection		X						
Design and development of Human centered intervention			X					
Heuristic evaluation			X					
Usability of the proposed system				X				
Refine the proposed SMAART Informatics self-management intervention				X				
Final deployment of the proposed SMAART informatics self-management intervention tool				X				
Study Recruitment (Baseline data)					X			
Follow up data collection					X	X		
Statistical analysis					X	X	X	
Report writing and manuscript preparation							X	X

Ethics and Dissemination

The study bearing protocol number PMCHRI-IHEC-067 gained approval from the Panimalar Medical College Hospital and Research Institute Institutional Human Ethics Committee (Central Drugs Standard Control Organization Registration No. ECR/1399/Inst/TN/2020) in March 2022 with approval No. PMCH&RI/IHEC/2021/078 dated March 15, 2022. The study will be conducted according to the Declaration of Helsinki, as it involves human participants [29]. The study is in accordance with the STROBE Guideline for case-control studies [30]. The findings of the study will be disseminated through peer-reviewed publications and national and international conference presentations.

Results

In order to reduce the health inequity in India, it is imperative to have the requisite knowledge base. The present study would help to fill the research and knowledge gap by identifying key areas that need to be addressed to improve the health status of the population. The baseline data will enable us to find the socio-economic inequity faced by the participants, their health literacy, their awareness regarding their health status and health care. These findings would also help to design and develop tailored population health intervention(s) to enhance the healthy eating and active living of the population groups.

Discussion

Health inequities have existed throughout as also resonated by the concept of inverse care law (1971), which highlighted how good medical care is inversely related to people's needs in Low- and Middle-Income Countries [31]. Similarly, Cookson R et al., recently proposed the law of disproportionate care (2021) where they argue that in High Income countries socially disadvantaged groups receive more care but of worse quality to meet their healthcare needs [32]. The available studies also reinstate the need to address the health inequities by collecting and analysing the relevant health equity data [33]. The present study would therefore help in filling the requisite knowledge gaps by identifying the key determinants of health inequity. It would also help in contributing to the advancement of evidence base for strategic decisions on health inequity. The findings from this research project would also help in designing, developing, and implementing data-driven, evidence-based, and human-centred interventions to enhance the healthy eating and active living of the population groups.

Limitations

The study's limitations include that it is confined to one geographic region only implementing it in diverse geographic and population setting would help in better understanding and comparing the impact of the HEAL intervention.

Conclusion

HEAL intervention offer a model to enhance the healthy eating and active living for the individuals participating in the study through SMAART framework. The findings from the study will contribute to the understanding of the role of digital health interventions to enhance healthy eating and active living of the population groups which will help in understanding and addressing determinants of health equity in the population.

Acknowledgments

The authors are the only contributors to this manuscript and are acknowledged.

Data

availability:
The data that support the findings of this study will be available on
request from the
corresponding author.

Authors' Contributions

All authors have contributed to the design of the study, development of the questionnaire, preparation of the manuscript, and have approved the manuscript for publication.

Conflicts of Interest

None declared.

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Abbreviations

WHO: World Health Organization

SDGs: Sustainable Development Goals

CDC: Centers for Disease Control and Prevention

NCDS: Non-Communicable Diseases

DASS: Depression Anxiety, and Stress Scale

Annexure:

STROBE Statement—Checklist of items that should be included in reports of *case-control studies*

	Item No	Recommendation	Page No	Line No.
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1	3, 20
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	1	11-42
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	2,3	69-80
Objectives	3	State specific objectives, including any prespecified hypotheses	3	81-89
Methods				
Study design	4	Present key elements of study design early in the paper	3,4	94-123
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4,5	124-125, 221-224
Participants	6	(a) Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls	4	124-135
		(b) For matched studies, give matching criteria and the number of controls per case	NA	

Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5	163-205
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	NA	
Bias	9	Describe any efforts to address potential sources of bias	NA	
Study size	10	Explain how the study size was arrived at	NA	
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5	\163-205
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	5	213-220
		(b) Describe any methods used to examine subgroups and interactions	5	213-220
		(c) Explain how missing data were addressed	5	213-220
		(d) If applicable, explain how matching of cases and controls was addressed	5	213-220
		(e) Describe any sensitivity analyses	5	213-220
Results				
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	NA	
		(b) Give reasons for non-participation at each stage	NA	
		(c) Consider use of a flow diagram	NA	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	NA	
		(b) Indicate number of participants with missing data for each variable of interest	NA	
Outcome data	15*	Report numbers in each exposure category, or summary measures of exposure	NA	

Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	NA
		(b) Report category boundaries when continuous variables were categorized	NA
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	NA
Discussion			
Key results	18	Summarise key results with reference to study objectives	NA
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	NA
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	NA
Generalisability	21	Discuss the generalisability (external validity) of the study results	NA
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	NA

*NA- Not applicable

Supplementary Files

Multimedia Appendixes

Untitled.

URL: <http://asset.jmir.pub/assets/6e759365453733807ff44a2f31ddaf1d.docx>

CONSORT (or other) checklists

Strobe checklist.

URL: <http://asset.jmir.pub/assets/10e4a441d4eb5ebb9ff1167f04722404.pdf>