

Enhancement of Self-Management of Metabolic Syndrome (MetS) among adults in urban poor settings of India using Digital Health Intervention: Protocol for a Mixed Methods Study

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Abstract

Background: Prevalence of Metabolic Syndrome (MetS) is increasing among the adult population of India. Urban poor adapt to an urbanized lifestyle, which places them at a higher risk for obesity, diabetes, and hypertension. Along with that, they have poor access to healthcare, high out-of-pocket expenditure, poor purchasing ability, and food availability. In India, there is a paucity of data on the interplay of several risk variables in the increased burden of MetS among adults in urban slums settings. There is a limited information on multifaceted interventions useful for the self-management of cardio-metabolic risk factors leading to MetS.

Objective: The objective of the proposed study is to design, develop, and pilot test an interactive, tailored, internet and mobile-enabled digital health intervention to enhance self-management of MetS among individuals living in urban poor settings of New Delhi, India.

Methods: The study employs mixed methods to meet the set objectives.

Results: The study is ethically approved by the Institutional Ethics Committee of ICMR- National Institute of Pathology. The findings will be disseminated to the national and international scientific community and published in peer-reviewed publications.

Conclusions: The study anticipates enhancement of self-management of MetS among individuals living in urban slum settings. The findings from this study will help understand and expand the role of digital health interventions to enhance self-management of MetS.

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Original Manuscript

Protocol

Enhancement of Self-Management of Metabolic Syndrome (MetS) among adults in urban poor settings of India using Digital Health Intervention: Protocol for a Mixed Methods Study

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Abstract

Background: Metabolic Syndrome (MetS) is a growing concern among the adult population in India, particularly among the urban poor. The challenge of this group is a combination of risk factors including an urbanized lifestyle, poor access to healthcare, and financial limitations, leading to high levels of obesity, diabetes, and hypertension.

Objective: The current study aims to address this challenge by designing, developing, and piloting a tailored, mobile-enabled interactive digital health intervention to enhance self-management of MetS among individuals living in urban slums of New Delhi, India.

Methods: The study employs mixed methods, including both quantitative and qualitative data collection to design and evaluate the effectiveness of the intervention that is built on a multifactorial model in improving the self-management of MetS. Data will be collected at baseline and 12 months from the urban slums of Delhi.

Results: The findings will be disseminated to both national and international audiences through peer-reviewed publications. The results will contribute to our understanding of the interplay of risk factors in MetS and the impact of tailored digital health interventions in addressing this challenge.

Conclusions: The study is expected to provide valuable insights into the role of digital health interventions in enhancing self-management of MetS among the urban poor population.

Keywords: Digital health Intervention; Metabolic syndrome; Cardio-metabolic risk factors; Mixed methods; Self-management.

Introduction

Background and Rationale

Metabolic Syndrome (MetS) also known as “Syndrome X” poses a growing threat to public health. By 2020, Cardiovascular Diseases (CVD) are projected to be the leading cause of death and disability in India, with 2.6 million deaths expected [1]. Meanwhile, stroke, a major contributor to CVD, is projected to increase to 894 per 100,000 people [2]. MetS is characterized by a cluster of metabolic factors including high BP, impaired glucose tolerance or diabetes, dyslipidemia (elevated levels of triglycerides (TG) and low concentration of High-Density Lipoproteins) marked by the presence of abdominal obesity [3]. The specific etiology of the metabolic syndrome remains unclear but an interplay between genetic, behavioral, clinical, and environmental factors such as

urbanization, mechanization, and rural-to-urban migration play an important role in the etiological risk factor of MetS [1,3–5].

Although there are numerous studies on the effects of health interventions for nutrition and physical activity on single risk factors such as obesity, CVD's and diabetes [6][7] have been no studies evaluating the impact of multifactorial interventions. The role of social determinants of health in reducing the burden of MetS has not been considered in these studies. As per preventive measures, changes through intervention in dietary habits and physical activity are key lifestyle changes recommended by medical literature[8–10]. Despite increased public awareness about Non-Communicable Diseases (NCDs) the burden of NCDs has not decreased.

Slum residents' individual behaviors in their environment are crucial in understanding the causes of NCDs, and cannot be tackled through policy recommendations based on lumped quantitative data alone. This ignores the interplay of culture, politics, poverty, economics, and actions in slum conditions and the role of the Sustainable Development Goals (SDG) [11]. Given the concentration of health programs and policy resources in cities, it is assumed that city inhabitants have more access to services like rehabilitation and health care, and that poor people in cities are thus better off than their rural counterparts. This is where the vulnerability of the urban poor arises; the issue of equality becomes critical for the urban poor, who face complicated and debilitating issues such as the inability to pay for products and services, and a lack of social support structures. The urban poor also has economic hurdles when it comes to making healthier dietary decisions. Access, availability, and affordability of ultra-processed, high-sugar, high-fat foods over fresh fruits, vegetables, and meat have set the platform for high risk for Metabolic syndrome. A few barriers to telehealth interventions identified in the Indian context stand true to the urban poor population groups like Digital divide, Language barriers, Perceived usefulness/preference for face-to-face consultation, Perceived ease of use, etc,[12]. Food environments, food security, Sanitation and hygiene, clean drinking water and such are contributing factors to the urban poor falling susceptible to metabolic syndrome[13,14].

Prior studies found that individuals treated for diabetes or hypertension only often received medications and do not adopt lifestyle changes such as consuming a healthier diet and increasing physical activity [15]. There is a dearth of effective intervention models that are feasible in Indian rural poor-resource settings against significant challenges owing to poverty, low literacy, and gender norms[16]. Interventions to address social, behavioral, and environmental determinants of MetS and cardio-metabolic disorders are less developed[17]. Hence, the creation of science-based, behavior-focused, context-specific, and culturally relevant interventions taking into account the social determinants of health data is the solution to address the burden of MetS. Therefore the proposed study aims to fill existing gaps in understanding how cardio-metabolic and environmental factors interact and influence the self-management of MetS among urban poor populations.

Study Aim and Objectives:

This study aims to design, develop, and pilot test an interactive, tailored, internet and mobile mobile-enabled health intervention to enhance self-management of MetS among individuals living in urban poor settings.

Following are the three objectives of the study proposed to fulfill the aim:

- To develop a model that examines cardio-metabolic risk factors such as diet and physical activity, stress, and sleep and their interplay with the living environment in facilitating self-management of MetS among adults living in urban poor settings of New Delhi.
- To design and develop an interactive digital health intervention to enhance the self-management of MetS based on the findings of objective one.
- To pilot test the utility and feasibility of the proposed digital health intervention platform among adults living in urban poor settings to help them self-manage their MetS.

Methods

Study Design and Population:

To achieve objective one, a mixed-method approach comprising of qualitative and quantitative assessments will be used to develop a model that will describe the interplay between the living environment and other cardio-metabolic risk factors such as diet, physical activity, stress, and sleep. The in-depth interviews will be among a sample population of 120 participants enrolled across urban slum settings across four zones of New Delhi (North, South, East, and West).

To achieve objective two, a quasi-experimental study design will be used in a sample of 80 participants, with a human-centered approach to design and develop an interactive, tailored mobile and internet-enabled digital health intervention platform. The findings of objective one will help in defining the essential elements and features of the proposed digital health intervention platform. The findings

Objective three of the study will be to pilot test the utility and feasibility of the proposed digital health intervention and to measure the usage, adherence, satisfaction, and acceptance of the proposed digital health intervention. For this, a sample size of 30 people will be employed from each of the eight slums (240 participants) of New Delhi. The methodology has been presented graphically in Figure 1.

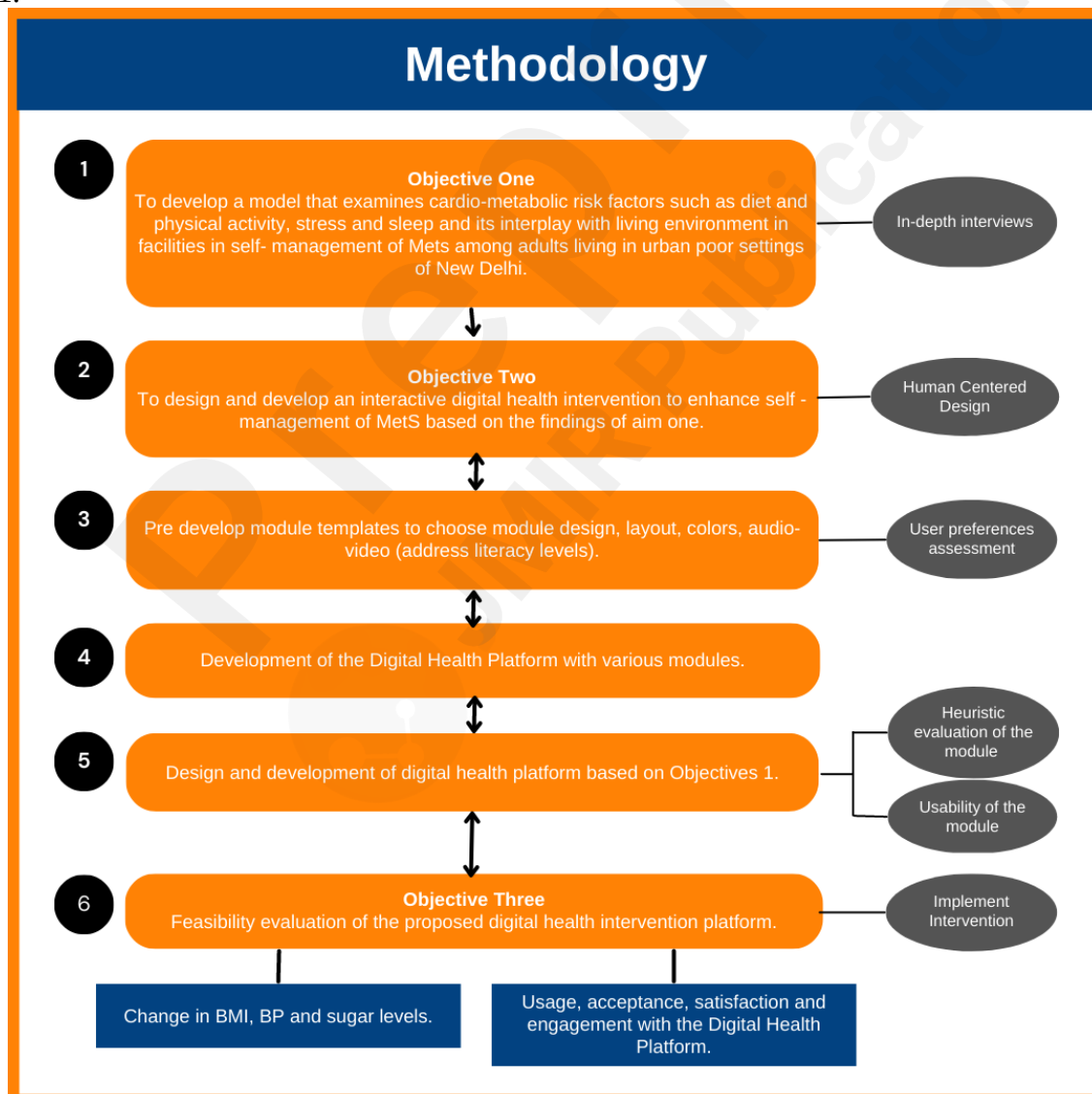


Figure 1: Flowchart of study methodology.

Inclusion and exclusion criteria:

Eligible participants will include adults (18 years and above) those who have given informed consent, have an android phone and are willing to use technology, those available for follow-up interviews and those diagnosed with metabolic syndrome (Presence of three of the five risk factors of MetS). Individuals below age 18, have a terminal illness, impaired cognition, presence of co-existing illness documented in the medical record (type 1 diabetes) or self-reported associated with systemic inflammation (e.g. rheumatoid arthritis, acute systemic infection); Pregnant or lactating women; involved in other clinical trials or protocols related to MetS, those failing to adhere to study procedures (e.g., scheduled surgery, travel plans or scheduling difficulties that do not permit full participation) will be excluded from the study.

Collection and storage of data: Data will be collected by trained data collectors electronically using tabs, and saved on the servers.

Informed consent:

Written informed consent to participate in the study will be obtained from each of the selected participants. Audio recording of consent will be done for uneducated individuals. Complete data confidentiality and anonymity of study participants will be ensured. Study consent will be available in English and a local Indian dialect.

Variable Assessment:

Socio-demographic profile: Data regarding age, income levels, employment status, education level, smoking, and alcohol status. Information gathered about prior use of computers, their frequency of usage, prior use of the internet, and sources of health information are captured.

Medical history: The medical history of the participant will be gathered by taking in medical records of the participant, asking for the history of identified NCDs, and taking note of prescriptions and medications used.

Laboratory Assessment: Assessment of blood sugar, HbA1C, and blood pressure levels assessed at baseline and the end of 12 months.

Anthropometric status: Height, weight, and waist circumference will be collected using a standard technique. Body mass index (BMI) is computed from height and weight measurements.

24-hour Dietary Recall: A standard protocol will be used to assess the dietary intake of the previous 24 hours. The methodology will include visual aids (photographs of servings) to assist them in accurate reporting of food intake.

Dietary Diversity Questionnaire: The FAO's Individual dietary diversity Score (IDDS) tool will be used to assess diversity in the diets of the individual participants; The tool comprises 16 food groups, of which nine will be analyzed. Diets comprising foods from ≤ 3 groups will be categorized as low IDDS, diets meeting 4-5 food groups are moderate diversity and those > 6 groups are diets of high diversity.

Perceived Stress Scale: The Perceived stress scale (PSS)[18] is the most widely used psychological instrument for measuring the perception of stress. It is a measure of the degree to which situations are appraised as stressful.

Physical activity assessment: Participants' physical activity will be assessed using the Global Physical Activity Questionnaire (GPAQ)[19]. The questionnaire will calculate the total time spent in physical activity for recreation, occupation, household work, and transportation in the last seven days.

MEDFICTS Dietary Assessment Questionnaire: The MEDFICTS questionnaire consists of eight food categories: Meat, Eggs, Dairy, Fried foods, fat in baked goods, Convenience foods, , and

Snacks. It is an efficient tool to quickly assess the adherence of participants to the fat components of a diet and identify those consuming a diet higher in total fat, saturated fat, and cholesterol.

Satisfaction to digital health intervention platform: It will be measured using the CSQ-Client Satisfaction Questionnaire-8 question. This eight-item questionnaire is a self-report statement of satisfaction with the intervention platform.

Acceptance of the digital health intervention platform: The technology acceptance questionnaire comprised 25 questions based on the Technology Acceptance Model with 6 constructs: (1) perceived ease of use, (2) perceived usefulness, (3) attitude, (4) behavioral intention, (5) self-efficacy, and (6) subjective norm.

Engagement with the digital health intervention platform: Number of times of weekly Logins, completion of tasks promptly and submitting their day-to-day data.

The Pittsburgh Sleep Quality Index: The Pittsburgh Sleep Quality Index (PSQI) is a self-rated questionnaire that will be used to assess sleep quality and disturbances over a 1-month time interval. Nineteen individual items generate seven "component" scores: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction. The sum of scores for these seven components yields one global score

System Usability Scale (SUS): SUS questionnaire assesses the appropriateness of the application functionality and the Usability of the digital health intervention. It also assesses the extent to which users view the application as support for their goals and tasks and checks for interfaces' usability.

Health Knowledge, Attitude, and Practice Assessment:

Data is assessed on the knowledge of MetS, risk factors of co-morbidities, attitude to health-related choices, and practice patterns. The KAP assessments are an informative tool and are bound to change with time. The assessment employed at different time points can help identify key changes and effects of the intervention.

Adherence to Medication:

Two questionnaires are used to assess participants' adherence to medication. Adherence is a crucial part of the prognosis of any disease. The Morisky Scale for medical adherence is a short assessment scored on patient responses. These tools assess the attitude behind adherence, the challenges to it, and the convenience or ease of medication which is a critical point of adherence.

The Summary of Diabetes Self-Care Activities:

The information regarding self-care activities among patients with diabetes will be collected using the revised version of the summary diabetes and hypertension self-care activities questionnaire (SDSCA). The core questionnaire components with a few more questions concerning each of the components along with items on medication practices will be assessed.**Data Analysis plan:**

The gathered variable outcome data will be checked for inconsistencies or missing values and will be confidentially stored and retrieved for analysis. The qualitative (In-depth interviews) data will be analyzed by content analyses. Descriptive analyses will report the means and SDs of data results. T-tests will be used to compare the means between categorical and continuous variables. Chi-square analysis will be used to analyze categorical variables. Univariate and Bivariate analyses of independent variables will be done. Reporting of results will be done at a 95% Confidence Interval and P=0.49 used.

Project timelines:

The detailed project timelines and schedule in correspondence with the study objectives are presented in Table 1.

Table 1. Study timelines

Objectives	Task	Month							
		1	2-3	4-6	7-14	15-20	31-32	32-33	34-36
Preparatory phase									
1	Stakeholder meeting	X	–	–	–	–	–	–	–
	In-depth interviews	–	X	X	–	–	–	–	–
	Analysis of qualitative in-depth interviews data	–	–	X	–	–	–	–	–
Intervention and Development									
2	Design and development of Human-centered intervention	–	–	–	X	–	–	–	–
	Heuristic evaluation	–	–	–	X	–	–	–	–
	Usability of the proposed system	–	–	–	X	–	–	–	–
	Refine the proposed digital health self-management intervention	–	–	–	X	–	–	–	–
3	Final deployment of the proposed digital health self-management intervention	–	–	–	–	X	–	–	–
Data collection									
4	Study Recruitment	–	–	–	–	X	–	–	–
	Baseline and Follow up data collection	–	–	–	–	X	X	–	–
5	Statistical analysis	–	–	–	–	X	X	X	–
	Report writing and manuscript preparation	–	–	–	–	–	–	X	X

Quality Assurance: Quality Assurance: Data collection and entry will be done by trained field staff following standard techniques and protocols. Training sessions for the field workers will be held to acquaint the data collection team with the study aim, objectives, study area, and inclusion/exclusion criteria. Information was also given for study instruments, anthropometric data collection, in-depth interviews (engagement with the respondent, probing), and informed consent (for data collection, audio recording, and pictures). To ensure efficiency and high-quality data collection and processing, weekly meetings with the field and research staff will be held. A log of all data collected will be maintained and weekly data checks will be done.

Ethical approval:

The study was approved by the Indian Council of Medical Research- National Institute of Pathology Institutional Human Ethics Committee in January 2022 with approval No. NIP-IEC/29-12-2021/05/01R1. The study will be conducted according to the Declaration of Helsinki, as it involves human participants [18].

Outcomes:

The study outcomes include the enhancement of self-management of MetS among individuals living in urban slum settings. The study will identify influencing risk factors on MetS and examine the role of digital interventions to address the risks. The authors also expect the study to increase self-efficacy and the Knowledge, attitudes, and practices related to self-management of diabetes and hypertension and other risk factors of MetS among individuals living in urban slum settings.

Results

The results of the proposed study will help provide an in-depth understanding of the interplay of the risk factors of MetS among the urban poor population. The study intervention will help improve adherence to interventions and promote self-management of prognosis. The study results will be disseminated at various levels including scientific journal publications, conference proceedings, etc.

Discussion

The paper aims to address the growing threat of metabolic syndrome (MetS) in India, where despite numerous studies on the effects of health interventions, there have been no evaluations of multifactorial interventions and the role of social determinants of health in reducing the burden of MetS has not been considered. The proposed digital health intervention model will utilize principles of a human-centered approach involving users' input throughout the design and development of the intervention. The authors aim to fill the gap in understanding the interaction between cardio-metabolic and environmental factors and self-management of MetS among urban poor populations. The results of the study are expected to increase knowledge, attitudes, and practices related to self-management of metabolic syndrome and other risk factors among urban poor populations. However, the study has limitations, such as being limited to urban poor populations only and facing challenges in the implementation of interventions, which may limit its generalizability. The findings from the study will contribute to the understanding of the role of digital health interventions in enhancing the self-management of metabolic syndrome that will greatly impact public health at large. ,

Acknowledgments

All authors have contributed to this manuscript. All authors provide their consent to the publication of this protocol. The authors would like to acknowledge the funding and support of ICMR.

Data availability:

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

Conflicts of Interest

None declared

Abbreviations

FAO: Food and Agriculture Organization

ICMR: The Indian Council of Medical Research

Multimedia Appendix 1

Appendix attached.

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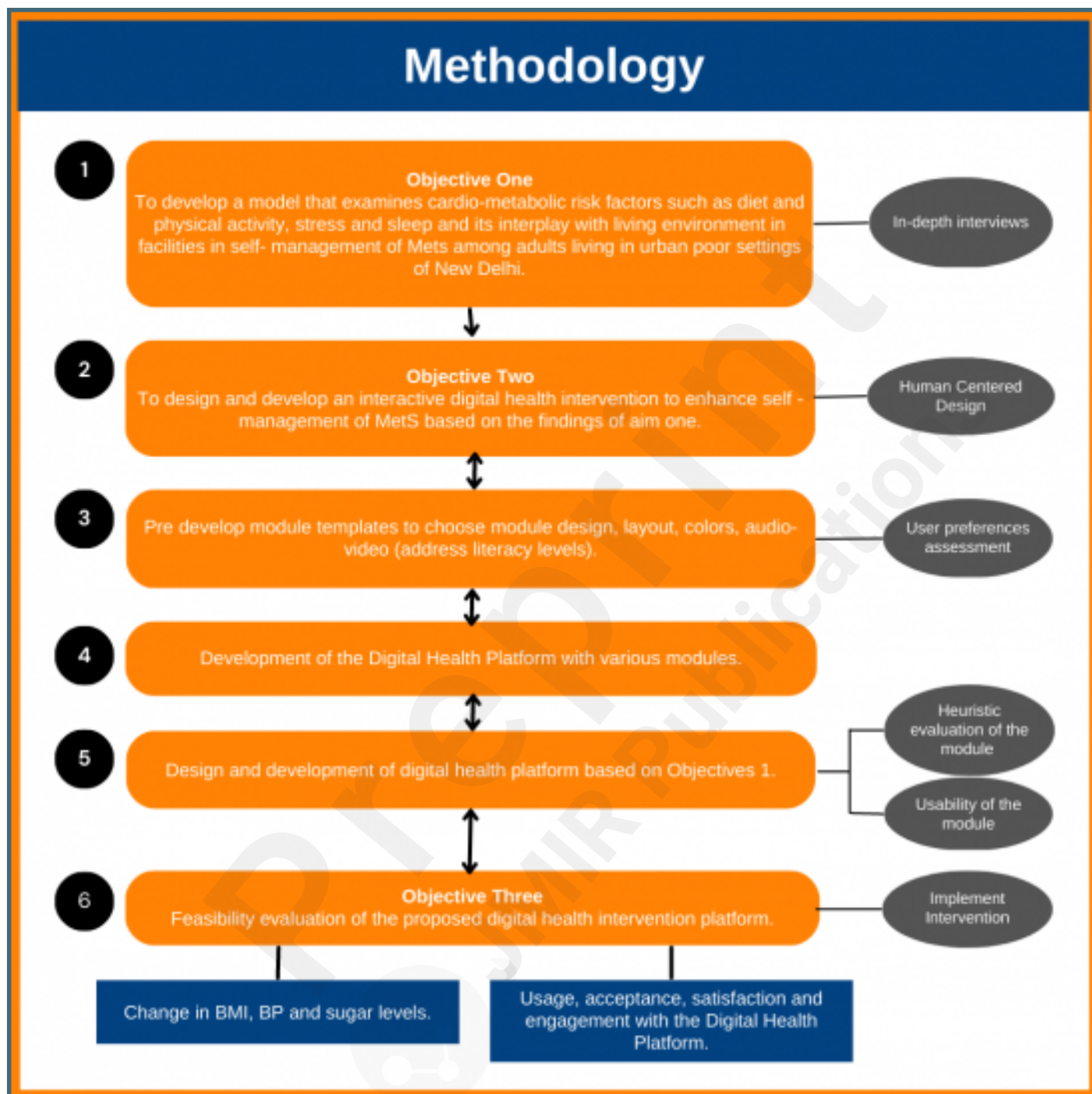
Supplementary Files

Manuscript with track changes.

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Figures

Flowchart of study methodology.



Multimedia Appendixes

Tools.

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