Effectiveness of mHealth program on blood pressure among prehypertensive young adults: Protocol of a Pragmatic Cluster Randomized Controlled Trial

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Abstract

Background: The prevalence of prehypertension may be underreported because of its asymptomatic nature. The study will use a pragmatic mHealth application for delivering the intervention, which is expected to be well-received by the young population.

Objective: The study aims to assess the prevalence of prehypertension among young adults and evaluate the effectiveness of a mHealth intervention in enhancing adherence to lifestyle practices, knowledge on prehypertension and hypertension, and blood pressure among participants in the experimental and control groups.

Methods: The study will be conducted in two phases. Phase I will employ a cross-sectional survey design, and Phase II will include a pragmatic randomized controlled trial with cluster randomization.The protocol was prepared according to the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) 2013 checklist. The CONSORT 2017 guideline was followed in reporting the protocol. The estimated sample size for Phase I is 762, and the sample size for the Phase II is 85 per group. Both the control and experimental groups will receive education on prehypertension and hypertension, with the experimental group additionally receiving a mHealth app. The experimental group's adherence to lifestyle practices will be monitored every 15 days, and reminder messages will be sent to non-responders. Both groups will be followed up onsite at 1, 3, and 6 months to assess their knowledge on prehypertension and hypertension, blood pressure, and lifestyle practices.

Results: The primary outcome of the study will be an improvement in blood pressure readings. The secondary outcomes will include adherence to lifestyle practices and knowledge on prehypertension and hypertension. The study is ongoing, and as of July 2024, Phase I is completed with the data collected from 762 sample from 8 randomly selected colleges from Udupi district. Currently, phase 2 is in process. The data will be analyzed using Jamovi 2.3.21.

Conclusions: Identifying high-risk groups of young adults with prehypertension enables early interventions to prevent future hypertension and related organ damage. The study will contribute to achieving Sustainable Development Goal 3, which focuses on ensuring good health and well-being. Clinical Trial: CTRI/2023/04/051784

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Conclusion: Identifying high-risk groups of young adults with prehypertension enables early interventions to prevent future hypertension and related organ damage. The study will contribute to achieving Sustainable Development Goal 3, which focuses on ensuring good health and well-being.

Keywords: Prehypertension; blood pressure; young adults; randomized controlled trial; mobile-based program; digital health intervention; global health

Introduction

Hypertension is the third most significant risk factor contributing to the burden of noncommunicable diseases (NCDs) and places a considerable public health burden on cardiovascular health in India.[1] According to the World Health Organization, hypertension is a leading cause of premature death, with prehypertension serving as a critical precursor to hypertension both nationally and globally.[2] The Seventh Report of the Joint National Committee (JNC-7) classifies prehypertension as the systolic blood pressure (SBP) of 120–139 mmHg or the diastolic blood pressure (DBP) of 80–89 mmHg.[3] However, the Eighth Report of the Joint National Committee guidelines do not define prehypertension because their recommendations focus on individuals with diagnosed hypertension.[4] Despite the rising prevalence, increased awareness, and available treatments, hypertension remains poorly controlled, particularly in low- and middle-income countries, leading to major cardiovascular events.[2]

A study conducted in India revealed that the prevalence of hypertension and prehypertension among young adults is 11.2% and 33.3%, respectively.[5] Individuals with a family history of hypertension and those who are physically inactive have a higher risk of hypertension.[6] Identifying prehypertension during its asymptomatic stage allows for timely interventions to normalize blood pressure, thereby preventing or delaying the onset of hypertension.[7]

Many young adults with increased blood pressure remain undiagnosed, and a substantial proportion of individuals are unaware of their existing prehypertension. Young people are one of India’s most

valuable resources. Studies in India reported the prevalence of prehypertension among young adults to be in the range 24.6%–65%.[5,7,8,9,10,11,12,13]

Mobile devices have become integral to healthcare, providing easy access to health information both at home and on the go.[14] Early identification of prehypertension enables proactive blood pressure management through preventive strategies, thereby reducing cardiovascular morbidity and mortality.

Globally, hypertension is the leading cause of death, accounting for 10.4 million deaths annually.[15] Prehypertension, the initial stage of hypertension, represents a critical point for intervention where appropriate measures can delay or prevent the progression to hypertension. In addition, prehypertension is associated with an increased risk of both hypertension and cardiovascular diseases (CVDs).[16]

A study conducted in the coastal villages of Udupi District in Southern India found that the prevalence of prehypertension among young adults (aged 20-30 years) was 45.2%. Biological factors, such as being in the 25-30 age group; preobesity and obesity; and behavioral factors, including sedentary occupations, excessive salt intake, and salty food consumption, were found to be associated with prehypertension.[7]

Globally, CVDs account for approximately 17.9 million deaths among middle-aged adults, with hypertension being the most common cardiovascular disorder, responsible for 20%–50% of all CVD-related deaths. Once considered a condition mainly affecting adults, hypertension is now increasingly prevalent among younger populations, with its onset reported even in childhood.[6,17]

Studies have reported a high prevalence of hypertension among Indian adults, with nearly one in three individuals having this condition. With approximately 762 million adults aged 18 years and older in India, this equates to an estimated 234 million adults with hypertension, indicating a significant future increase in the CVD burden. This finding highlights the urgent need for early detection and treatment because effective blood pressure control can prevent nearly one-third of all cardiovascular-related deaths.[15] In addition to blood pressure management, therapeutic strategies

should include modifying lifestyle, managing weight, and addressing other risk factors to reduce residual cardiovascular risk.[18,19]

Health education within the community is vital to increase awareness about hypertension and its risk factors among younger generations. Promoting physical activity and healthy eating is critical to counter the rapid rise of NCDs in many developing countries. Leveraging modern information and communication technologies to deliver interventions for physical activity and dietary changes is particularly promising, given the increasing availability of these technologies in such regions.[17]

The prevalence of prehypertension among adolescents is rising, though it remains underreported. This condition often progresses to hypertension in adulthood, with young adults experiencing cardiovascular and cerebrovascular disorders before the age of 40 or 45 years. This leads to significant morbidity, mortality, and a substantial socioeconomic burden on society.[6,20] Given the severity of this problem, the present study aims to determine the prevalence of prehypertension and evaluate the effect of mHealth interventions on adherence to lifestyle practices, knowledge on prehypertension and hypertension, and blood pressure among young adults. The growing adolescent population in India and the increasing risk factors highlight the importance of primary prevention as a crucial strategy to combat this epidemic.

This study aims to contribute to Sustainable Development Goal 3 ensuring healthy lives and promoting well-being for all at all ages. The specific target is to reduce premature mortality from NCDs by one-third through prevention and treatment and to promote mental health and well-being by 2030.

Materials and Methods

The protocol follows the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) 2013 checklist and reported following the CONSORT 2017 (Consolidated Standards of Reporting Trials of Nonpharmacologic Interventions) guidelines).[25,27] SPIRIT is presented in Table 3.

Study Participants and Sampling: The study will be conducted in the Udupi District of Karnataka, which is divided into seven taluks (Udupi, Kundapur, Karkala, Hebri, Byndoor, Brahmavar, and Kapu). There are 33 private and 10 government-run first-grade colleges in the district. Young adults aged 18–25 years studying in first-grade degree colleges (B.Sc., B.Com, B.A) in Udupi District who meet the inclusion and exclusion criteria (Table 1) will be considered for the study.

The calculated sample size for Phase 1 was 381 using the formula for estimating a proportion.

$$n=\frac{\left(Z_{1-\frac{\alpha}{2}}\right)^2 P(1-P)}{d^2}$$

After multiplying by a design effect of 2 due to cluster sampling, the sample size was determined to be 762. This calculation assumes a prevalence of prehypertension among young adults to be 45% based on a previous study by Sanjay Kini et al at a 95% confidence level with a 5% margin of error (absolute precision).

The sample size for Phase 2 was 34 per group considering 38% anticipated population standard deviation of the primary outcome variable i.e the prevalence of prehypertension, obtained using the formula for repeated measures ANOVA.

$$n=\frac{2\left(Z_{1-\frac{\alpha}{2}}+Z_{1-\beta}\right)^2 \sigma^2\left[1+(m-1)\rho\right]}{m(d)^2}$$

Accounting for a 20% dropout rate, the final sample size was 43 per group. After multiplying by a design effect of 2 due to cluster randomization, the sample size was determined to be 85 per group.

Conceptual framework

The study is based on a conceptual framework modified from the PRECEDE-PROCEDE model[22,23] developed by Green & Kreuter in 2005 (Figure 1).

Predisposing factors include antecedents to behavior, such as demographic and clinical factors, knowledge, and lifestyle behaviors.

Enabling factors include existing knowledge on prehypertension and hypertension, lifestyle

practices, and annual family income.

Reinforcing factors include a family history of hypertension that encourages prompt health maintenance.

Intervening variables are the onsite awareness program and the mHealth app aimed at enhancing knowledge on prehypertension and hypertension as well as adherence to healthy lifestyle practices.

Outcome variables include blood pressure, knowledge on prehypertension and hypertension, and lifestyle practices.

Study Design

The study is designed to be carried out in 2 phases. A cross-sectional survey design will be used in Phase I. Because the study aims to evaluate the effect of the mHealth program on adherence to lifestyle practices, knowledge of prehypertension, and blood pressure, a pragmatic randomized controlled trial with cluster randomization will be implemented in Phase II.

Phase I: After obtaining administrative permission from the Institutional Research Committee, Institutional Ethical Committee, and Joint Director of Collegiate Education, Udupi District, taluks from Udupi District were randomly selected to collect data for assessing the prevalence of prehypertension in Phase 1. The data were collected from the young adults of first-grade degree colleges of randomly selected taluks. Baseline information, clinical variables, lifestyle practices, knowledge on prehypertension and hypertension, and blood pressure was measured for all participants from the selected colleges. An automated oscillometric machine (OMRON digital BP apparatus) was used to measure blood pressure after device calibration.As of July 2024, Phase I is completed with the data collected from 762 sample from randomly selected 8 colleges.

Phase II:

Colleges with prehypertensive students identified during Phase I were considered as clusters (N=8) and were allocated to the intervention (n=3) and control groups (n=3) by simple randomization

technique using the chit method. A random allocation sequence was generated by the research assistants who are not involved in the study. Since the research assistants are collecting the data and the researcher is not directly contacting the study participants, blinding the researcher could be achieved. Currently, phase 2 is in process. Both the control and intervention groups will receive education on prehypertension. The experimental group will also receive the mHealth app that provides information on prehypertension, risk factors for prehypertension, lifestyle modifications (including the Dietary Approach to Stop Hypertension (DASH) diet and exercise), and strategies for preventing hypertension and its complications. The mHealth app will be installed on the mobile devices of all students in the intervention group, and they will receive orientation on its use. The experimental group will be monitored for adherence to lifestyle practices every 15 days through the mobile app, and reinforcement and reminder messages will be sent to non-responders. All participants in the experimental group will receive a message of encouragement every 15 days to continue practicing the recommended lifestyle changes. Both groups will be followed up at 1, 3, and 6 months to assess their knowledge on prehypertension, adherence to lifestyle practices, height, weight, Body Mass Index (BMI), and blood pressure onsite. At the end of the study, an information booklet on prehypertension will be provided to every college in Udupi District that was included in the study. The CONSORT 2017 flowchart of the study is presented in Figure 2.[27,28,29,30]

Data collection procedure and instruments

The following tools are used for data collection. The baseline data will be collected using a tool with two sections: demographic proforma and clinical proforma. Adherence to lifestyle practices will be assessed using the adherence scale on lifestyle practices developed by the researcher, with a total score of 12. Adherence will be categorized as “adherent” for those achieving ≥80% (a score of ≥10) and “nonadherent” for those scoring <80% (a score of <10). A structured knowledge questionnaire on prehypertension and hypertension will be used to assess the knowledge on prehypertension and hypertension. The questionnaire consists of 30 items, with a total score of 30.

The items are based on the JNC 7 recommendations for nonpharmacological interventions in the management of prehypertension. Knowledge levels will be classified as poor (0–9), average (10–20), and good (21–30). Blood pressure will be assessed using a digital BP apparatus. Blood pressure will be measured after a 5–10 min rest period. Two readings will be taken 1–3 min apart, and the average will be calculated. In case of a difference of more than 5 mmHg between the two readings, an additional two readings will be obtained, and the average of these multiple readings will be used.21 Prehypertension will be identified among young adults based on the average of two blood pressure readings taken. A calibrated stadiometer and weighing machine will be used to assess the height and weight.

The validated tools will be tested for reliability by administering them to 20 students from selected degree colleges in Udupi District. The reliability of the structured knowledge questionnaire will be assessed using the split-half method. The tools will be pretested with 10 students from a degree college in Udupi District. A pilot study will be conducted with 20 students at a selected degree college.

Intervention

The intervention protocol includes an onsite awareness program on prehypertension and hypertension (Table 2) and an mHealth app that provides information on prehypertension, its risk factors, and lifestyle modifications, including the DASH diet and exercise, for preventing and managing the complications of prehypertension. The app’s user flow is depicted in Figure 3. Both the control and experimental groups will receive education on prehypertension and hypertension. The experimental group will be monitored every 15 days for adherence to lifestyle practices, with reminder messages sent to nonresponders, whereas responders will be encouraged to maintain their lifestyle changes. Both groups will be followed up at 1, 3, and 6 months, during which their knowledge of prehypertension and hypertension as well as their height, weight, BMI, and blood pressure will be assessed onsite.

Outcomes

The primary outcome is blood pressure and the secondary outcomes are adherence to lifestyle practices and knowledge on prehypertension and hypertension.

Statistical analysis

Data analysis will be conducted using Jamovi 2.3.21, employing both descriptive and inferential statistics in line with the study objectives. For descriptive statistics, mean and standard deviation will be used because all study outcomes are quantitative and continuous. Because the study involves assessing outcomes at four time points (baseline, 1st month, 3rd month, and 6th month), repeated measures ANOVA will be used to evaluate the effectiveness of the intervention.

Discussion

Globally, hypertension is responsible for 10.4 million deaths annually.[15] Prehypertension, an early stage of hypertension, can be effectively managed with proactive measures, thereby delaying or preventing the future risk of hypertension and its complications.[16]

Evidence from a study conducted in Southern India suggests that a 45.2% prevalence of prehypertension among young adults (aged 20–30 years). The study also revealed that prehypertension risk is associated with obesity and several lifestyle factors, including unhealthy dietary habits and occupation-related physical inactivity.[7] Although hypertension was once considered a disease of adults, studies now show an alarming rise in cases among younger age group.[2]

Cardiovascular disease accounts for approximately 17.9 million deaths globally among middle-aged adults, with 20%–50% of these deaths attributed to hypertension-related cardiovascular conditions.[2] In India, hypertension is highly prevalent, affecting one in three adults. With an estimated 762 million people aged 18 years or older in India, this translates to 234 million adults living with hypertension. The rising prevalence of hypertension, particularly among young adults, poses a significant socioeconomic burden if not addressed promptly.[9,18] Globally, the number of adults with

hypertension, estimated at 1 billion in 2000, is expected to double to 2 billion by 2025.[24] Research strongly supports the role of lifestyle interventions as an essential measure in effective blood pressure control and the reduction of CVD-related morbidity and mortality.[9,17,20]

Given the severity of this issue, this study is being undertaken. The growing population in India, coupled with increasing risk factors, indicates the importance of primary prevention as a critical strategy to combat this epidemic. A limitation of this study is that it is confined to young adults studying at first-grade degree colleges in Udupi District, Karnataka which restricts the generalizability of the findings.

Conclusion

Prehypertension is associated with a higher likelihood of developing hypertension and doubles the risk of cardiovascular events. In this study, mHealth interventions are designed to target individuals identified as prehypertensives. Further research is recommended to develop interventions that can detect early signs of CVDs in prehypertensive individuals. Because young adults represent the nation's most valuable resource and contribute significantly to its growth, prioritizing innovative interventions to combat prehypertension is essential for building a healthier nation.

Ethics and dissemination

The study protocol received institutional ethical approval on May 11, 2022 (IEC1 160/2022) and is registered under the Clinical Trial Registry of India (CTRI/2023/04/051784). Written informed consent will be obtained from all participants prior to data collection. The study will adhere to the guidelines of the Declaration of Helsinki.

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Author contributions

All authors have made significant contributions to the work, including conceptualization, execution, and critical review of the protocol, and agree to take responsibility for all aspects of the work.

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Competing interests

The authors declare no conflicts of interest. The protocol underwent independent peer review as part of the ICMR funding process.

References

1. Motiwala FF, Prasad GB, Shukla S, Nimbhore G, Thakare T, Patil S. Survey report of Prevalence of Hypertension in a Rural community. Homeopathy 2023; 7(2): 36-40.
2. Mills KT, Stefanescu A, He J. The global epidemiology of hypertension. Nat Rev Nephrol 2020;16(4):223-37.
3. Bharath T, Prarthana KG, Shrinidhi SP. A Preliminary Study of Prevalence of Prehypertension and Association of Body Mass Index with Blood Pressure in Prehypertensive Subjects. Sch. J. Appl. Med. Sci. 2015;20(32): 620-622. doi:10.36347/sjams.2015.v03i02.018.
4. Hernandez-Vila E. A review of the JNC 8 blood pressure guideline. Tex Heart Inst J 2015;42(3):226-8.
5. Geevar Z, Krishnan MN, Venugopal K, Sanjay G, Harikrishnan S, Mohanan PP, Mini GK, Thankappan KR. Prevalence, awareness, treatment, and control of hypertension in young adults (20–39 Years) in Kerala, South India. Front. cardiovasc. med. 2022;9:1-11. https://doi.org/10.3389%2Ffcvm.2022.765442.
6. Jayanthi R, Girijasivam SP, Nithyavikasini N, Gaur A. Prevalence of prehypertension in young adults in South India. NJPPP 2020;10(11):961-965.
7. Kini S, Kamath VG, Kulkarni MM, Kamath A, Shivalli S. Pre-hypertension among young adults (20–30 Years) in coastal villages of Udupi District in Southern India: an alarming scenario. PloS

one 2016;11(4):1-12. 10.1371/journal.pone.0154538.

8. Das SK, Sanyal K, Basu A. Study of urban community survey in India: growing trend of high prevalence of hypertension in a developing country. Int. J. Med. Sci. 2005;2(2):70-78. https://doi.org/10.7150%2Fijms.2.70.
9. Srinivas S, Satyavaraprasad K, Ramdas R, Krishna CP, Tajuddin T, Rao RP. Prevalence of prehypertension in adult population of rural Andhra Pradesh. AJBPS 2013; 3(23), 45-48.
10. Prabhakaran D, Shah P, Chaturvedi V, Ramakrishnan L, Manhapra A, Reddy KS. Cardiovascular risk factor prevalence among men in a large industry of northern India. NMJI 2005;18(2):59-65.
11. Mungreiphy NK, Dhall M, Tyagi R, Saluja K, Kumar A, Tungdim MG, Sinha R, Rongmei KS, Tandon K, Bhardwaj S, Kapoor AK. Ethnicity, obesity and health pattern among Indian population. J Nat Sc Biol Med 2012;3(1):52.
12. Gupta R, Deedwania PC, Achari V, Bhansali A, Gupta BK, Gupta A, Mahanta TG, Asirvatham AJ, Gupta S, Maheshwari A, Saboo B. Normotension, prehypertension, and hypertension in urban middle-class subjects in India: prevalence, awareness, treatment, and control. Am. J. Hypertens. 2013;26(1):83-94.
13. Bhardwaj R, Kandori A, Marwah R, Vaidya P, Singh B, Dhiman P, Sharma A. Prevalence, awareness and control of hypertension in rural communities of Himachal Pradesh. J Assoc Phys India 2010;58:423-429.
14. Yuting Z, Xiaodong T, Qun W. Effectiveness of a mHealth intervention on hypertension control in a low-resource rural setting: a randomized clinical trial. Public Health Front. 2023;11:1-12. https://doi.org/10.3389%2Ffpubh.2023.1049396.
15. Unger T, Borghi C, Charchar F, Khan NA, Poulter NR, Prabhakaran D, Ramirez A, Schlaich M, Stergiou GS, Tomaszewski M, Wainford RD. 2020 International Society of Hypertension global hypertension practice guidelines. J. Hypertens. 2020;75(6):1334-57.
16. Owiredu EW, Dontoh E, Essuman SE, Bazanfara BB. Demographic and lifestyle predictors of

prehypertension: A cross-sectional study among apparently healthy adults in Kumasi, Ghana. Biomed Res. Int. 2019;2019(1):1764079. doi:10.1155/2019/1764079.

17. Müller AM, Alley S, Schoeppe S, Vandelanotte C. The effectiveness of e-& mHealth interventions to promote physical activity and healthy diets in developing countries: A systematic review. Int J Behav Nutr Phys Act 2016;13:1-4. doi:10.1186/s12966-016-0434-2.
18. Ramakrishnan S, Zachariah G, Gupta K, Rao JS, Mohanan PP, Venugopal K, Sateesh S, Sethi R, Jain D, Bardolei N, Mani K. Prevalence of hypertension among Indian adults: results from the great India blood pressure survey. Indian Heart J 2019;71(4):309-13.
19. Tony L, Areekal B, Nair AT, Ramachandran R, Philip RR, Rajasi RS, Vijayakumar K. Prevalence of hypertension and pre-hypertension among adolescent school children in Thiruvananthapuram, Kerala, India. IJCMPH 2016;3(12):3556-63.
20. Babu, H., & Ganesh, N. Prevalence and Risk Factors of Hypertension and Prehypertension among Young Adults. IJCMSR 2020; 5(3): 89-92. doi:http://dx.doi.org/10.21276/ijcmsr.2020.5.3.23
21. Pickering TG, Hall JE, Appel LJ, Falkner BE, Graves J, Hill MN, Jones DW, Kurtz T, Sheps SG, Roccella EJ. Recommendations for blood pressure measurement in humans and experimental animals: part 1: blood pressure measurement in humans: a statement for professionals from the Subcommittee of Professional and Public Education of the American Heart Association Council on High Blood Pressure Research. Circ. 2005;111(5):697-716.
22. El Ashery Ashery Asker R, Mansuor Mostafa M, Ibrahem Abd El Fatah Yassen M. Effect of Educational Intervention Based on PRECEDE Model on Preventive Behaviors among High-Risk Individuals for Diabetes Type 2. Egypt. J. Health Care 2021;12(1):1217-29.
23. Pourhaji F, Delshad MH, Tavafian SS, Niknami S, Pourhaji F. Effects of educational program based on Precede-Proceed model in promoting low back pain behaviors (EPPLBP) in health care workers Shahid Beheshti University of medical sciences: randomized trial. Heliyon 2020;6(10).

10.1016/j.heliyon.2020.e05236.

24. Mhaske, N. S., & Dahanukar, S. Prehypertension in Adolescent Children. J. Hypertens. 2020; 9(1): 1-7. doi:10.24105/2167-1095.9.262.
25. Chan AW, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin JA, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jerić K. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. BMJ 2013;346.
26. Campbell MK, Piaggio G, Elbourne DR, Altman DG; CONSORT Group. Consort 2010 statement: extension to cluster randomized trials. BMJ 2012; 345: e5661. PMID: 22951546
27. Boutron I, Altman DG, Moher D, Schulz KF, Ravaud P, CONSORT NPT Group. CONSORT statement for randomized trials of nonpharmacologic treatments: a 2017 update and a CONSORT extension for nonpharmacologic trial abstracts. Ann Intern Med. 2017;167(1):40-7.
28. Gur S, Oztekin SD, Oztekin I, Yalcın O. The effects of Korean hand acupressure on postoperative pain, nausea, vomiting, and retching after thyroidectomy: A randomized controlled study protocol. J Educ Health Promot. 2024;13(1):347.
29. Nazmi S, Nikbakht HA, Gholamnia-Shirvani Z, Behmanesh F, Azizi A. The effectiveness of pubertal health group counseling based on problem-solving, on body image concerns and anxiety in adolescent girls: Study protocol. J Educ Health Promot. 2024 Jun 1;13(1):215.
30. Boutron I, Altman DG, Moher D, Schulz KF, Ravaud P, CONSORT NPT Group. CONSORT statement for randomized trials of nonpharmacologic treatments: a 2017 update and a CONSORT extension for nonpharmacologic trial abstracts. Ann Intern Med. 2017;167(1):40-7.

Table 1. Inclusion and Exclusion criteria for the study

Inclusion Criteria	Exclusion Criteria
Phase I	
• Young adults aged between 18-25 years studying in selected degree colleges of Udupi District, Karnataka. • Young adults willing to participate in the study.	• Young adults who are already diagnosed have hypertension and other systemic disorders. • Young adults who are on medications for any other ailments.
Phase 2	

• Young adults identified to have prehypertension in Phase 1. • Pre-hypertensive young adults willing to participate in the study. • Pre-hypertensive young adults having android mobile phones.	• Young adults who are identified to have hypertension in Phase 1 and already diagnosed have other systemic disorders. • Prehypertensive Young adults who are on medications for any other ailments. • Prehypertensive young adults who do not have android mobile phones.

Table 2. Plan for the mHealth intervention

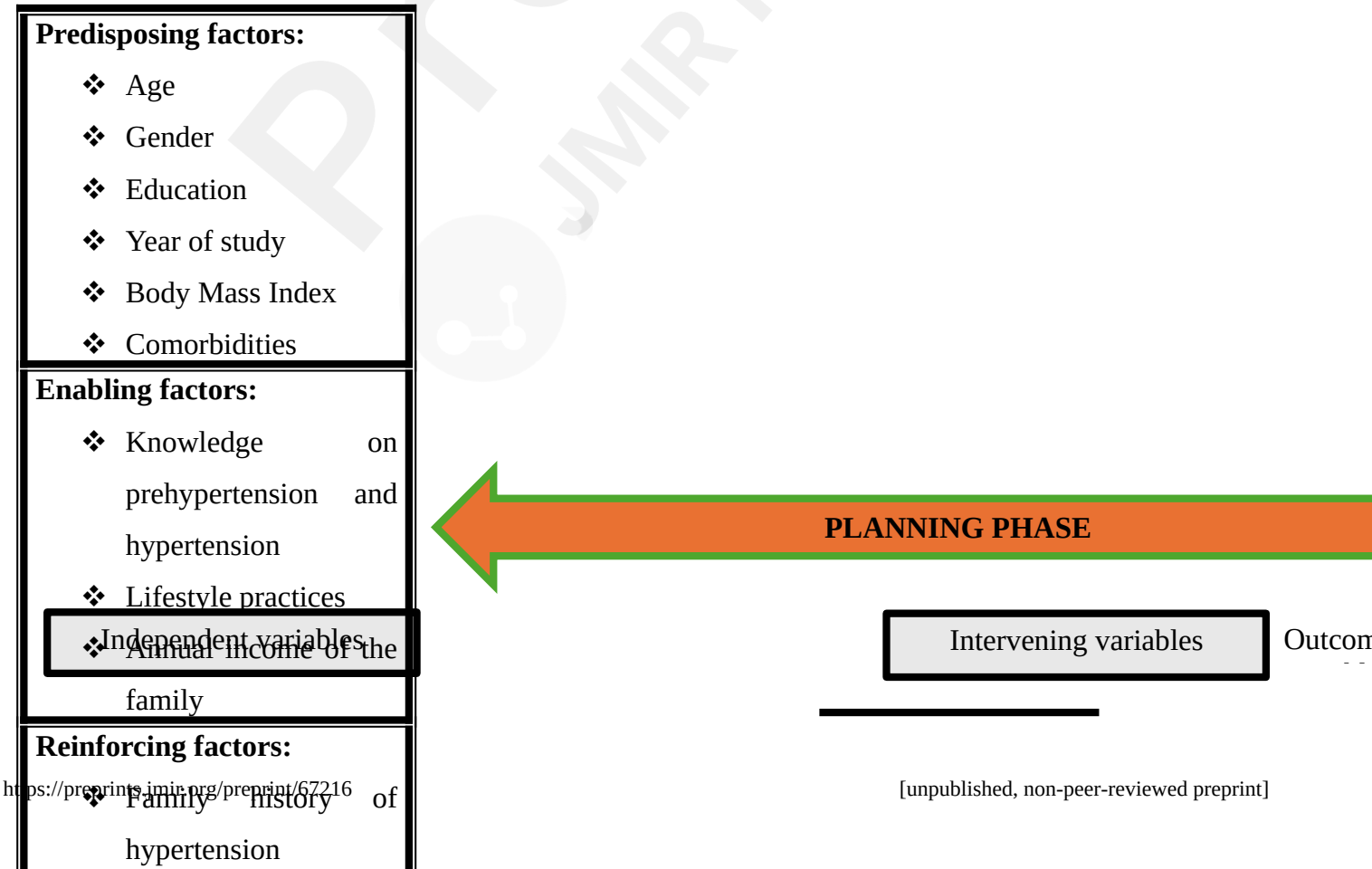
Areas of teaching in the teaching plan	**Duration**	**mHealth App**	**Information leaflet**
Introduction	2 minutes	The information in the app is provided under the following headings in both English and	The information leaflet encompassing the details of teaching
Meaning of Pre-hypertension	2 minutes		
Risk factors for pre-hypertension	5 minutes		
Lifestyle modifications for the control of blood pressure.	10 minutes		
Significance of adherence to	5 minutes		

lifestyle practices in controlling blood pressure.		Kannada language: • About Blood Pressure, Prehypertension and Hypertension • Diet • Exercises • Yoga • Smoking and Alcohol consumption • Sleep	provided during the onsite awareness program will be given to the participants of all the clusters after the study at the end of 6th month.
Role of diet in reducing blood pressure focusing on DASH diet guidelines.	5 minutes		
Conclusion	1 minute		
Discussion	15 minutes		
Total duration of teaching	45 minutes		

Table 3. Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)

Time Point	**Enrollment**	**Allocation**	**Post allocation**				
			Baseline	Once in 15 days	1st month	3rd month	6th month
Enrollment							
Eligibility screen	x						
Informed consent	x						

Allocation		x					
Interventions							
mHealth program on blood pressure			x				
Awareness program on prehypertension and adherence to lifestyle practices			x				
Assessments							
Demographic details	x		x				
Clinical details (Height, Weight, BMI, Blood Pressure)			x		x	x	x
Knowledge of Prehypertension and Hypertension			x		x	x	x
Adherence to lifestyle practices			x	x	x	x	x



Primary Outcome:

- Blood pressure

Secondary outcome:

- Lifestyle practices
- Knowledge on prehypertension and hypertension.

EVALUATION PHASE

FINISH

Figure 1. Conceptual framework on mHealth interventions for prehypertension among young adults modified based on PRECEDE-PROCEDE model developed by Green & Kreuter in the year 2005.

Enrolment

Assessed for eligibility (N=8 colleges as clusters)

Excluded:
Colleges who did not permit (N=0)
Not meeting inclusion criteria (N=0)
Colleges which are included for the pilot study (N=2)

Randomized (N=8)
Cluster size (n=170)

Allocation

Received allocated intervention (N=3)
Cluster size (n=85)
Baseline assessment: Demographic details, Clinical details (Height, Weight, BMI, Blood Pressure), adherence to lifestyle practices, knowledge on prehypertension.

Received allocated intervention (N=3)
Cluster size (n=85)
Awareness programme on prehypertension and hypertension, adherence to lifestyle practices.

Repeat Measurement (at one month, 3 months, and 6

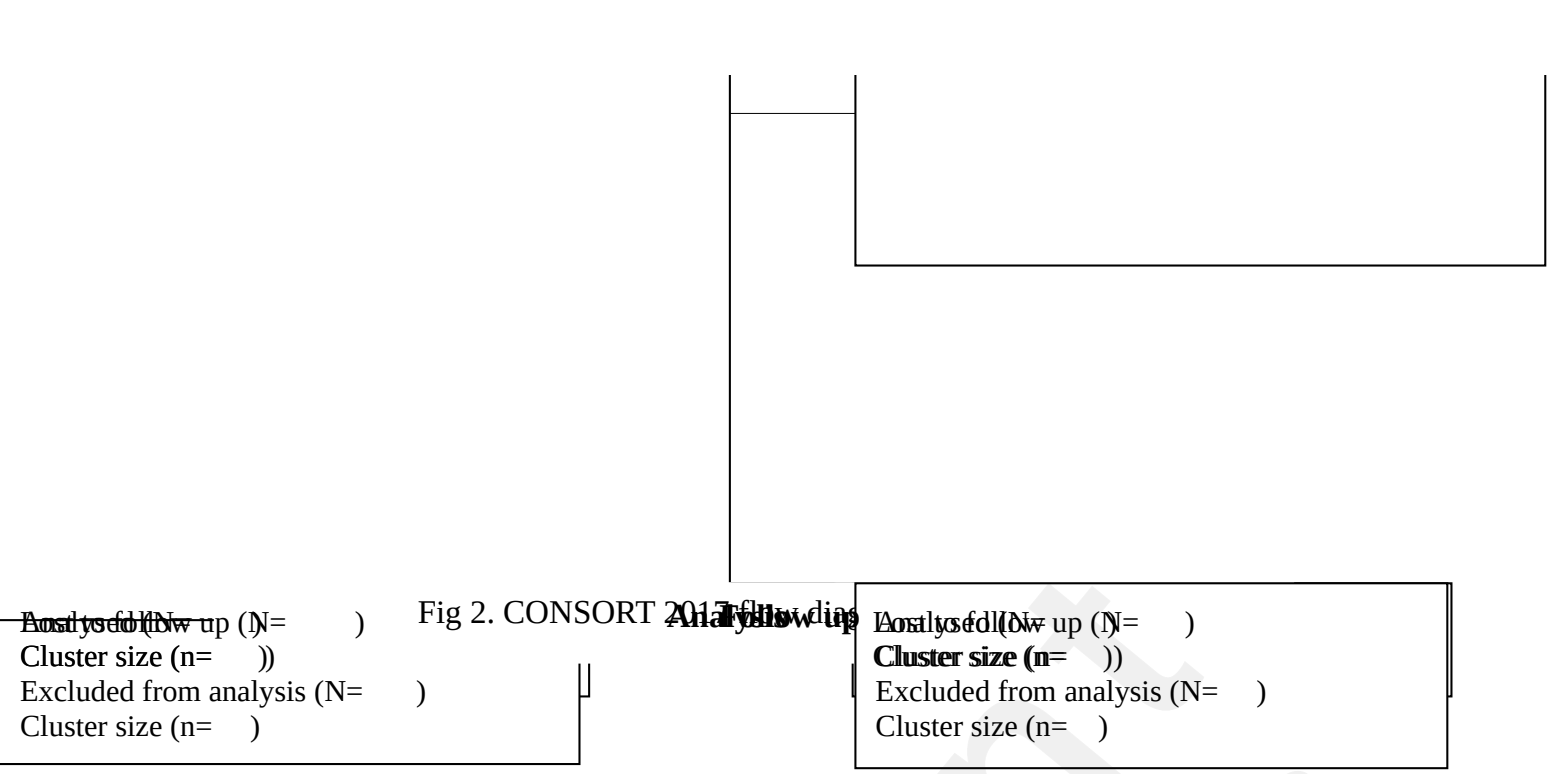


Fig 2. CONSORT 2017 flow diagram

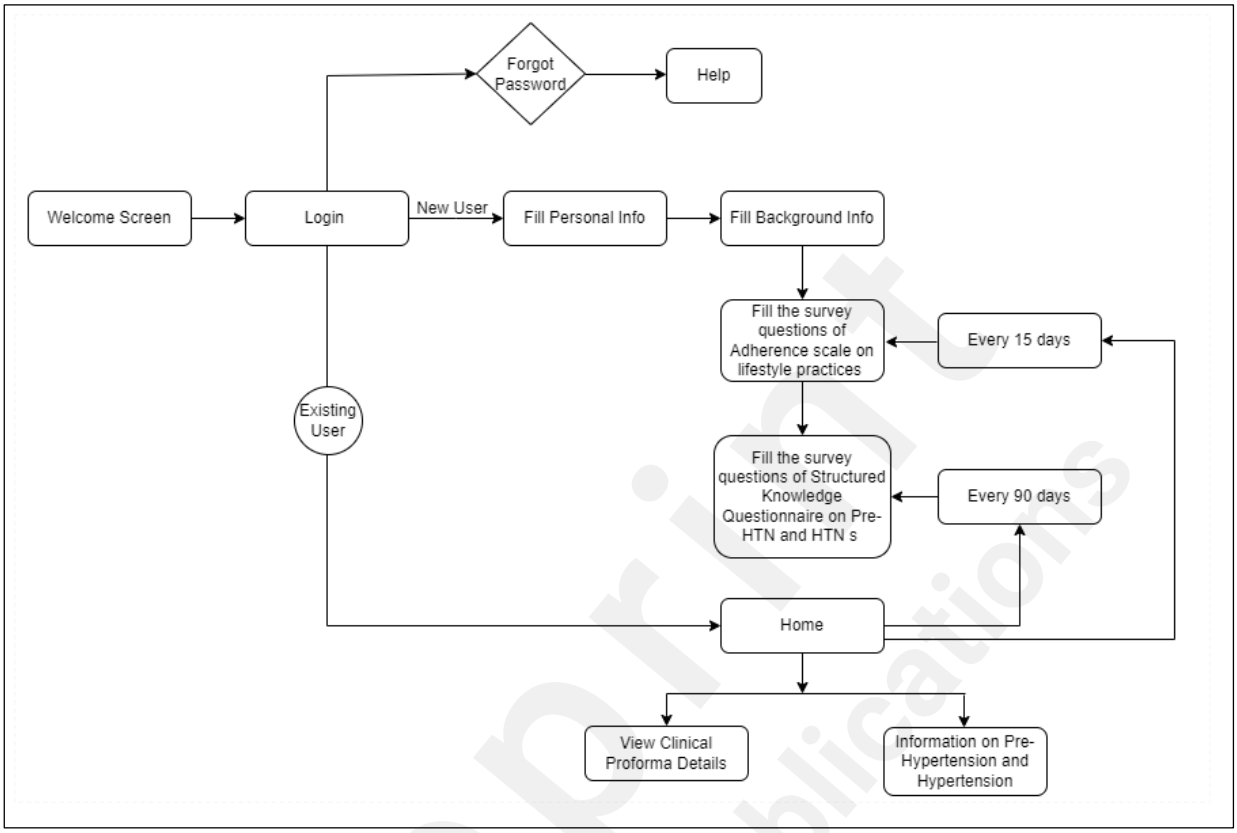


Figure 3. User flow diagram for the mHealth app on prehypertension

Supplementary Files

Figures

Conceptual framework on mHealth interventions for prehypertension among young adults modified based on PRECEDE-PROCEDE model developed by Green & Kreuter in the year 2005.

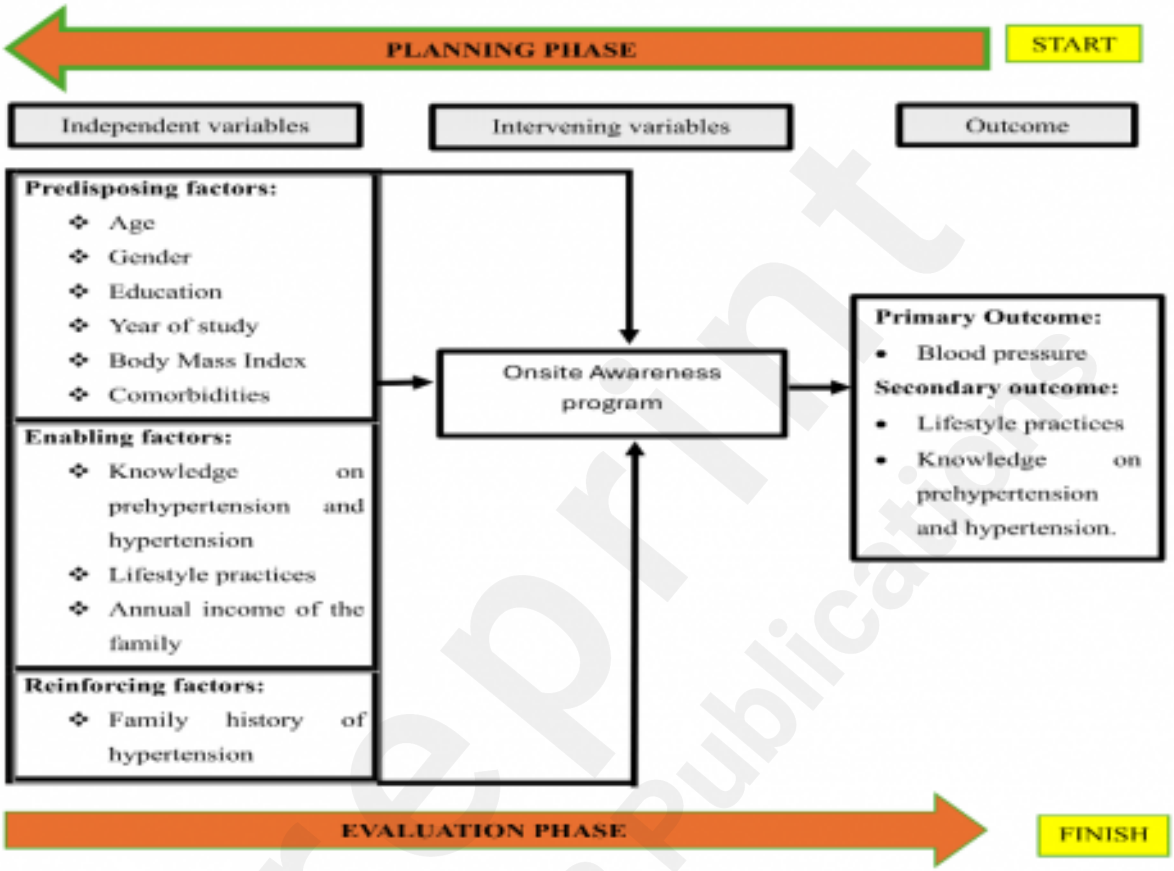


Figure 1. Conceptual framework on mHealth interventions for prehypertension among young adults modified based on PRECEDE-PROCEDE model developed by Green & Kreuter in the year 2005.

CONSORT 2017 flow diagram for the study.

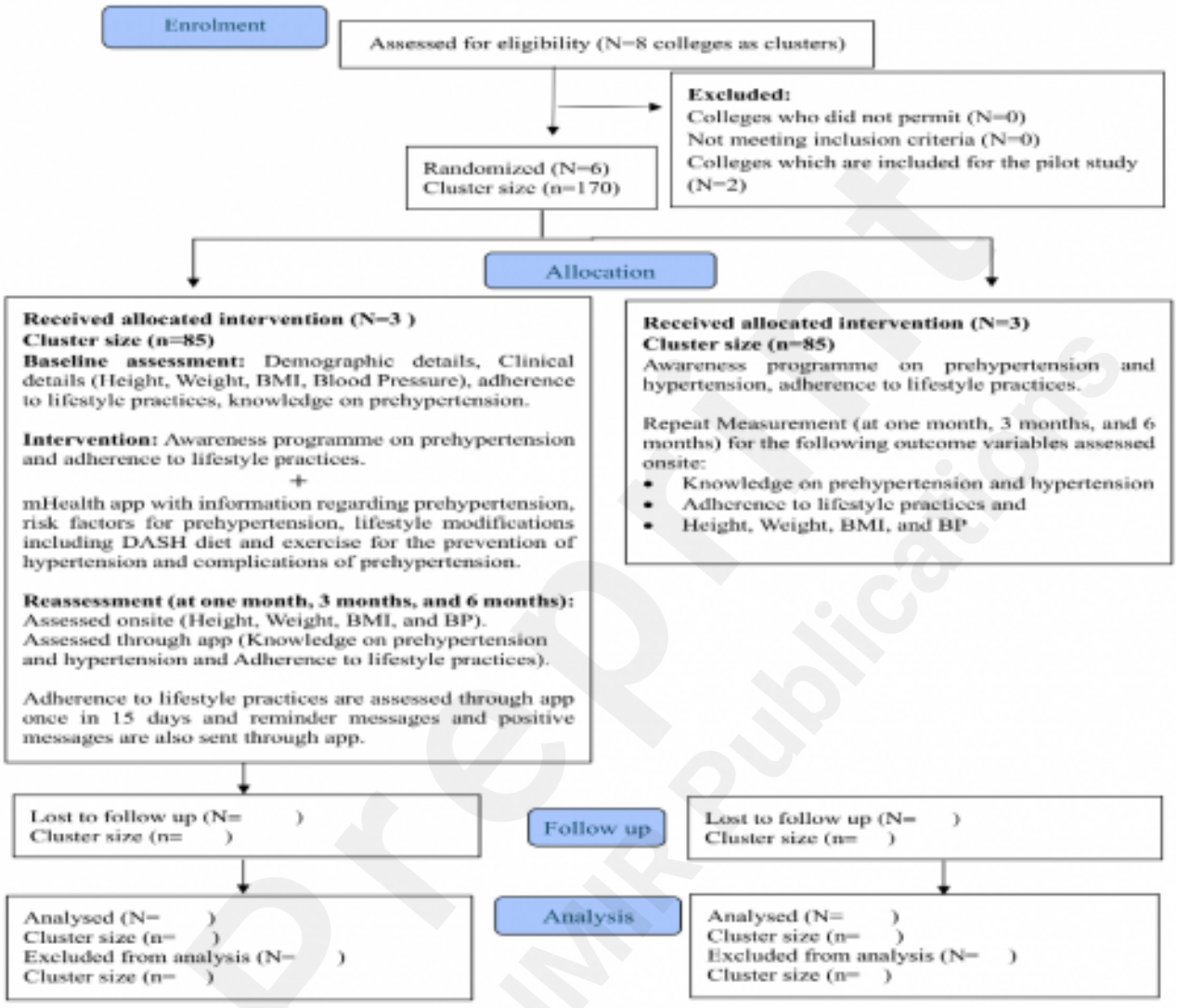


Figure 2. CONSORT 2017 flow diagram for the study.

User flow diagram for the mHealth app on prehypertension.

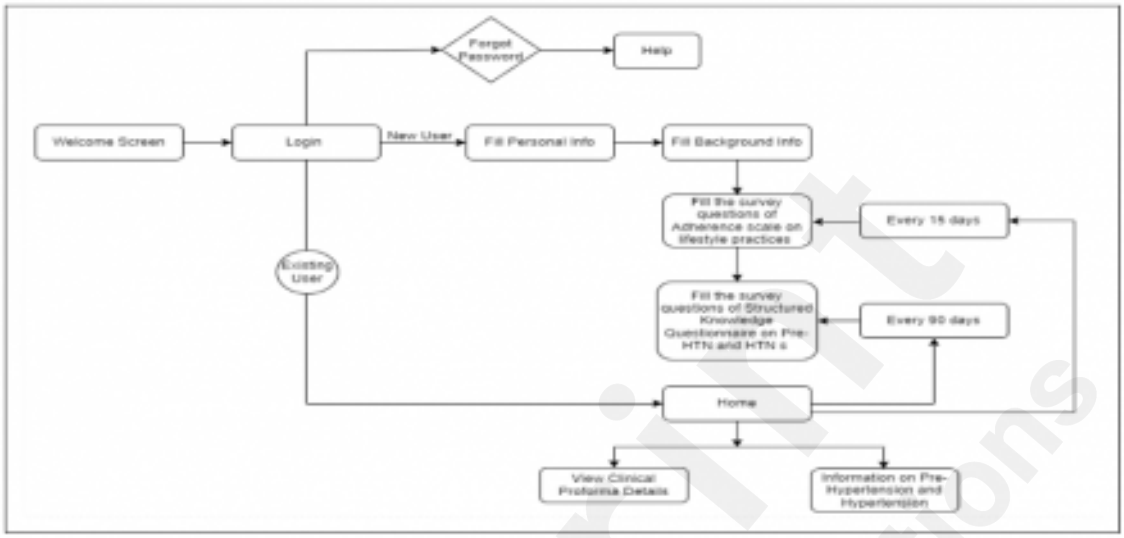


Figure 3. User flow diagram for the mHealth app on prehypertension.

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