

AIMS Faculty Research Proposal

ITEMS		
1.	Title of Research Study:	Effectiveness of a community-based education and peer support led by women self-help group members in improving the control of hypertension: an implement research in urban slums of Kochi city, Kerala, India
2.	Study Objectives:	
	Primary:	To assess the effectiveness of a community-based education and peer support led by women self-help group members in reducing the mean systolic blood pressure among people with hypertension in urban slums of Kochi Corporation, Kerala, India
	Secondary	To assess the effectiveness of the programme in improving hypertension self-care behavior (diet, physical activity, smoking) and adherence to medications in the same population To study the acceptability, adoption, appropriateness, feasibility, fidelity, cost effectiveness and coverage of community-based education and peer support led by women self-help group members in the same population
3.	Background, Rationale & Current relevance of the proposed study	
	Background and summary of key findings from the Literature Review	<p>Kerala, a state in southern India has achieved impressive improvements in health as many of its social and health indicators like Human development index (0.84), Infant mortality rate (6/1000), sex ratio (1084 females to 1000 males) and Female literacy (93%) are at par with most of the developed countries.(1) Cardiovascular Disease (CVD) mortality rate in Kerala is alarmingly as high as 382 per 100000 for men and 128 for women; the prevalence of CVD has almost tripled over two decades.(2-4) Hypertension is directly responsible for 57% of all stroke deaths and 24% of all coronary heart disease deaths in India.(5) Prevalence of hypertension among people above 18 years in Kerala was reported to be as high as 40%.(6,7) Recent observations indicate that only approximately half of the people with a diagnosis of hypertension in Kerala receive treatment and, of this population, only 30% have their blood pressure within the therapeutic target.(6,7)</p> <p>A study to estimate the prevalence of Hypertension in Kochi found that the overall prevalence of hypertension was 40.8% (95% CI 39.4-42.2)(7) Among them nearly 50% were newly detected and among the known hypertensive, nearly two third had uncontrolled hypertension. The study also found that high salt intake (OR 3.62) and poor adherence to medication (OR 4.45) were associated with uncontrolled hypertension status. (8) Another study done to estimate the prevalence of adherence to hypertensive medication has shown that adherence was not good in 54% of people with hypertension and on treatment. Risk factors of poor adherence identified were poor knowledge of the complications (OR 2.12), availing treatment from Government pharmacy (OR 2.37) and being asymptomatic at the time of diagnosis (OR 3.34). Nearly 75% were getting treatment from private clinics/hospitals and about half (48.7%) of the respondents reported that it took less than 15 minutes for them to reach the healthcare facility they consult. 85% had an out of pocket expenditure for treatment of hypertension and the mean monthly expenditure among those had an out of pocket</p>

	<p>expenditure on medicines was Rs.772.62±935.6 which is 4.77±4.23% of the monthly family income. (9)</p> <p>“Kudumbasree units” in Kerala- Women Self Help Groups under the leadership of Local Self Governments are one of the largest women empowering projects in the country. (10) The programme makes all the effort to alleviate poverty through an integrated approach involving effective union of resources and action. It combines different kind of activities like thrift and credit, micro enterprises, income generating activities and a wide range of welfare activities. Kudumbashree chooses a family based approach; it reaches the family through women and the community through these families. Neighbourhood group is the lowest tier consisting of 15 to 30 women members. Meetings are arranged on a weekly basis, in the house of one of the NHG members.</p> <p>Peer support is increasingly being explored as a possible solution for populations with limited access to healthcare. There is growing evidence that Peer support is an effective tool to improve health outcomes and long term management of chronic diseases.(11-16) A meta-analysis of 17 studies shown that peer support interventions for diabetes overall achieved a statistically significant but minor improvement in HbA1c levels.(17) Involving women self-help group members for early diagnosis of hypertension in the community and building their capacity as peer educators will be a potentially low-cost, flexible means to supplement formal health care support and will ensure community participation for health. There are mixed results for the effectiveness of community health workers (CHWs) in identification and management of cardiovascular disease in various settings in India. (18,19)</p> <p>Reference</p> <ol style="list-style-type: none"> 1. Government of India. National Family Health Survey-4 (NFHS-4) 2015-16. State Fact Sheet. Kerala. Ministry of Health and Family Welfare, GOI. New Delhi 2016. Available from: http://rchiips.org/NFHS/pdf/NFHS4/KL_FactSheet.pdf [accessed on July 12, 2017] 2. Soman CR, Kutty VR, Safraj S, Vijayakumar K, Rajamohanan K, Ajayan K. AllCause Mortality and Cardiovascular Mortality in Kerala State of India: Results From a 5-Year Follow-up of 161 942 Rural Community Dwelling Adults. <i>Asia Pac J Public Health</i>. May 10 2010. 3. Krishnan MN, Zacharia G, Venugopal K. Prevalence of coronary artery disease and coronary risk factors in Kerala, south India-a community based cross sectional study. <i>BMC cardiovasc disord</i>. 2016;16:12
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	<p>4. Kutty VR, Balakrishnan KG, Jayasree AK, Thomas J. Prevalence of coronary heart disease in the rural population of Thiruvananthapuram district, Kerala, India. <i>Int J Cardiol.</i> 1993;39:59–70</p> <p>5. Murray CJ, Lopez AD. Mortality by cause for eight regions of the world: Global Burden of Disease Study. <i>Lancet.</i> 1997;349:1269–76</p> <p>6. Thankappan KR, Shah B, Mathur P, et al. Risk factor profile for chronic noncommunicable diseases: results of a community-based study in Kerala, India. <i>Indian J Med Res</i> 2010;131:53–63. 6.</p> <p>7. Jishnu SL et al. Prevalence and correlates of uncontrolled hypertension in Kochi city, Kerala, southern India [Dissertation] Kochi;Amrita Viswavidhyapeetham;2016 10.</p> <p>8. Thankappan KR, Sivasankaran S, Sarma PS, et al. Prevalence-correlates-awareness treatment and control of hypertension in Kumarakom, Kerala: baseline results of a community-based intervention program. <i>Indian Heart J</i> 2006;58:28–33.</p> <p>9. Arjun B et al. Adherence to hypertension treatment- cross sectional study from urban slums, Kerala, India [unpublished]</p> <p>10. Government of Kerala. Kudumbasree[Internet]. Thiruvananthapuram. [cited Nov 1, 2016]. Available from: http://www.kudumbashree.org/</p> <p>11. Funnel MM. Peer support education and mentoring. <i>Diabetes Self Manag</i> 2010;27(8); 11-5</p> <p>12. Fisher et al. Peer support of complex health behaviors in prevention and disease management with special reference to diabetes: systematic review. <i>Clin Diab Endo.</i>2017;3(4)</p> <p>13. Brownstein JN, Chowdhury FM, Norris SL, Horsley T, Jack L. Effectiveness of community health workers in the care of people with hypertension. <i>Am J Prev Med.</i> 2007;32(5):435–447.</p> <p>14. Fisher EB, Coufal MM, Parada H, Robinette JB, Tang P, Urlaub D et al. Peer support in health care and prevention: cultural, organizational and dissemination issues. In: Fielding J, Brownson RC, Green L, et al., editors. <i>Annu rev Public health.</i> Volume 35. Palo Alto: Annual Reviews; 2014. pp. 363–</p>
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		<p>383.</p> <p>15. Norris SL, Chowdhury FM, Van Le K, et al. Effectiveness of community health workers in the care of persons with diabetes. <i>Diabetic Med</i> 2006;23:544–568</p> <p>16. Riddell MA, Renwick C, Wolfe R, et al. Cluster randomized controlled trial of a peer support program for people with diabetes: study protocol for the Australasian Peers for Progress study. <i>BMC Public Health</i> 2012;12:843.</p> <p>17. Werfalli M, Raubenheimer P, Engel M, et al. Effectiveness of community-based peer-led diabetes selfmanagement programmes (COMP-DSMP) for improving clinical outcomes and quality of life of adults with diabetes in primary care settings in low and middle-income countries (LMIC): a systematic review and meta-analysis. <i>BMJ Open</i> 2015;5:e007635.</p> <p>18. Joshi R, Chow CK, Raju PK, et al. The Rural Andhra Pradesh Cardiovascular Prevention Study (RAPCAPS): a cluster randomized trial. <i>J Am Coll Cardiol</i> 2012;59:1188–96. 47.</p> <p>19. Prabhakaran D, Jeemon P, Goenka S, et al. Impact of a worksite intervention program on cardiovascular risk factors: a demonstration project in an Indian industrial population. <i>J Am Coll Cardiol</i> 2009;53:1718–28.</p> <p>20. He J, Irazola V, Mills K, et al. Effect of a Community Health Worker-Led Multicomponent Intervention on Blood Pressure Control in Low-income Patients in Argentina. <i>JAMA</i> (Accepted for publication August 2017).</p>
	Rationale of the Study:	<p>Community participation is an essential component for ensuring primary health care. Communities that begin to understand their health status rather may be moved to take a series of preventive measures and health education is most effective in the context of community activities. Volunteers for health from community might have the confidence of the people. Peer support is increasingly being explored as a possible solution for populations with limited access to healthcare.</p> <p>If the program is shown to be feasible and effective, the results will be used to make recommendations and dissemination plans on how to implement and sustain it at similar settings within Kerala and outside. Potential for scalability is huge considering the large number of SHG s in the country. Components for diabetes and hypercholesterolemia control could be integrated</p>

		in a phased manner. Lessons from this study will contribute to disease prevention at a global level as the lessons learnt could be suitably adapted across other similar settings in low and middle-income countries.
4.	Study Description	
	(a) Study Design	Implementation Research- Cluster Randomized Control Trial
	(b) Study setting	The Corporation of Kochi is the largest municipal corporation in Kerala both in area and population. This is the second most important port city in the western coast of India and is the commercial capital of the State. There are 231 slums in Kochi city. The total households in all the slums were estimated as 12,949 with a total population of 60678 which constitutes nearly 11% of population of the City. Primary health care system in City, like other urban areas in Kerala, was not well established and was functioning sub optimally with weak referral system and inadequate attention to public health till recently when 16 urban Primary Health Centers were set up in Kochi city under National Urban Health Mission. The study will be carried out in 20 randomly selected slums in Kochi city.
	(c) Study Methodology	<p>Summary of study methodology attached as Fig 1 at the end of this document.</p> <p>Step 1: Consultation meeting with Self Help Group (SHG) group members, Local Self Government (LSG) leaders and intended participant group for finalising the intervention strategy: Involving the community in planning community intervention will be beneficial to check for its feasibility and sustainability. A consultation workshop will be designed with an objective to exchange information and to discuss the strengths, weaknesses, opportunities and threats of the proposed intervention; and to obtain perception of the stakeholders regarding the intervention and to finalise the intervention. Active discussion will be entertained in a welcoming environment. 15 people with hypertension, 5 primary care takers of people with hypertension, 15 local self- help group members, 5 elected local self -government representatives, 5 primary health care workers and 5 experts will be invited for a full and to obtain perception of the stakeholders regarding the intervention and to finalise the intervention. Active</p>

		<p>discussion will be entertained in a welcoming environment. 15 people with hypertension, 5 primary care takers of people with hypertension, 15 local self-help group members, 5 elected local self-government 3 representatives, 5 primary health care workers and 5 experts will be invited for a full day workshop. The research idea and intervention will be presented to them. They will discuss together about feasibility and sustainability of the intervention. They will be divided in groups to discuss the SWOT of the intervention. Modification in intervention strategies will be welcomed and will be finalised.</p> <p>Step 2: Developing and testing the training curriculum: A training module will be developed consisting of 20 sections. The modules will include a facilitator's guide, participant's guide, PowerPoint presentations, and exercises with problem solving skills and demonstration sections of Blood pressure and anthropometry measurement. It will include overview of Cardiovascular Diseases, normal values of BP, Blood sugar and anthropometric measurements, complications of hypertension and diabetes mellitus, evidence based locally adapted practical diet and physical activity recommendations, smoking cessation assessment and tips to encourage quitting, communication skills, Behaviour Change Communication strategies, practise session on using health education materials, measurement and recording of BP and weight, DOs and DONTs in patient support group meetings, initiating and supporting self-management of hypertension by the participants through goal-setting and maintaining records of each meeting and participant. The curriculum will be finalised in a two day workshop with 20 experts in the field. Initial training will be conducted for 20 SHG members with an intention to pilot test the module. A pre and post-test with 20 questions and 2 Objectively Structured Practical skills will be conducted. After each session and at the end of the workshop feed-back will be sought from the participants regarding the content and methodology. The module will be modified based on their feed backs.</p>
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	<p>Step 3: Cluster randomised pragmatic trial to test effectiveness of the interventions</p> <p>a. Recruitment strategies 20 urban slums will be selected using simple random sampling. A house to house survey will be conducted by trained data collectors. All those who are above the age of 18 years and are permanent residents of the place will be included in the survey. Standardised clinical measurements will be collected as follows; arterial BP after the participant has sat quietly for at least 5 min. BP is measured at least three times at using the appropriate cuff size and a Digital Automatic Blood Pressure Monitor according to the WHO STEPS protocol. Measurement continues until two consecutive readings differ by</p> <p>b. Selecting SHG Volunteers Concerned Local Self Government division counsellor (elected representative) in the intervention areas will be requested to nominate one Self Help Group members per 20 houses. The criteria for selecting SHG member will be given to LSG counsellor as a women staying in the community, acceptable to most of the households and is interested in doing volunteer health activity. Identified SHG members will undergo three days training (21 hours) in batches of 20.</p> <p>c. Inclusion criteria for participants The SHG members from intervention area will meet all those who had higher blood pressure in the houses allotted to them and invite them for intervention. All those who are above the age of 18 years and are permanent residents of the place with any of the following criteria will be included a) Indicate they are aware of being hypertensive b) are identified as having an average SBP of ≥ 140 mm Hg and/or DBP ≥ 90 mm Hg at the cross sectional survey, subsequently attend their primary healthcare provider and are then formally clinically diagnosed with hypertension. Verification occurs by sourcing the medical record, contacting the healthcare provider or by confirmation of use of medication(s) for hypertension c) have an average BP of ≥ 140 mm Hg SBP and/or ≥ 90 mm Hg DBP during the baseline survey and then, at the time of recruitment to the intervention (or control), have their BP</p>
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	<p>remeasured, and are found to still have an average BP of ≥ 140 mm Hg SBP and/or ≥ 90 mm Hg DBP. Pregnant women will be excluded.</p> <p>d Intervention Package The four key functions of SHG members in this study will be: (i) assistance in daily hypertension management; (ii) social and emotional support to encourage management of behaviors; (iii) linkage to primary health care system and community resources; and (iv) ongoing availability of support for chronic disease management and co-morbidity</p> <p>e1. Intervention 1- Group meetings SHG members are expected to organise once a month group meetings at a location decided by the community members. Each meeting will last for an hour. First 15 minutes will be presentation on a topic by SHG member using flip chart. Participants will be asked to reflect their views and clarify doubts on the topic. Then they can share their experiences during the month including the difficulties they face and innovative methods they used to control hypertension and diabetes mellitus. Last 15 minutes will be for discussing another priority health issue in the community. Health education will be delivered using pictorial flip charts on the following topics- one topic per meeting in serial order 1) Introduction- What is hypertension? Normal ranges of BP. Chronic nature of hypertension. Complications of hypertension and Need to maintain normal BP, 2) 10 ways to reduce hypertension- Overview, 3) Dietary modifications desirable to reduce Blood pressure, 4) Benefits of exercise and need to be physically active, 5) Need for medication adherence and tips to ensure that and 6) Smoking as a risk factor for hypertension and methods to quit. LSGD leader (Elected representative) will be invited to visit at least one meeting. Members from primary health care team (ASHA, Mutipurpose health workers) will also be invited for all the meetings. Next of kin or additional support persons will also be encouraged to accompany the person with hypertension at each group meeting. 5</p>
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		<p>e 2. Intervention 2- Monthly visits to participants SHG member will record Blood Pressure and weight, counsel on diet, physical activity and smoking cessation on a monthly basis. They will help in assisting with goal setting and support for behavioural change. They will also enquire about medication adherence and will link them to primary health system, if desired. They are expected to visit members who did not attend the meeting and brief them about the meeting proceedings.</p> <p>e 3. Maintaining Reports SHG members will maintain a report which includes details of the meetings such as the number of enrolled participants and community members attending the meeting, and major activities undertaken during the meeting. Additional activities by the SHG member to extend the healthy behaviour messages, such as tobacco cessation and physical activity, as well as behaviours specific to the management of hypertension from the meeting to the wider community will also be mentioned in the report book. They also need to maintain participant record capturing individual information and follow-up details of each participant.</p>
	(d) Study duration:	Total duration of the study is 18 months. Intervention will be for 6 months.
5.	Study tools:	<p>Indicators for outcome assessment and their measurements are shown in Table 1 at the end of this document. Community will be revisited after 6–10 weeks after the last meeting (after 6 months of intervention) to complete final data collection. Changes in continuous and categorical variables are assessed relative to their values determined at baseline. These include Systolic BP, Diastolic BP, BMI. Medication initiation and any dosage changes (observed and documented) will be recorded. Change in diet practices and physical activity over the 2 weeks prior to final administration of the questionnaire will be assessed. Coverage: overall response rate (people with hypertension, number participated in meetings, number visited by SHG members) will be calculated and participants who discontinue the programme will be asked to complete a</p>

		<p>programme evaluation form. Barriers to attending the meetings will be assessed, as are engagement and usage of health services during the period of the intervention. Costs effectiveness of the intervention will be assessed from a societal perspective. Acceptability, adoption and appropriateness will be assessed using Focus group discussions with beneficiaries (2 per each slum in the intervention arm till saturation), SHG members (2 FGDs) and LSGD leaders (1 FGD). Ethnography and narrative approach will be used to describe main factors influencing the implementation in the given context. Meeting report will be used for the assessment of fidelity of the meeting structure and content to the protocol.</p>
6.	Sample size and Sampling Technique:	<p>20 urban slums will be selected using simple random sampling. A house to house survey will be conducted by trained data collectors. All those who are above the age of 18 years and are permanent residents of the place will be included in the survey. Slums will be randomised in to two. One arm (10 slums) for peer support intervention led by SHG members and other (10 slums) serve as controls. Only external intervention in control areas will be the baseline and outcome assessment surveys..</p> <p>Average number of eligible participants in each slum will be around 100, considering 20% non-participation. Thus there will be a total of 1000 participants per arm (10 clusters on each arm and 100 participants per cluster). With an ICC of BP measurement in the community as 0.027 (obtained from a similar study done in Argentina), this will give an effective sample size of 275 on each arm, which has 91% power to detect a 5mm of Hg reduction in systolic BP, with 95% confidence, SD of parameter as 20mm of Hg and assuming ICC of BP reduction as 0.8.²⁰ Since this study incorporates a variety of non-pharmacological interventions and also tries to generate demand for pharmacological interventions, improve medication adherence and establish referral linkages, expecting a reduction of 5mm of Hg is justified.^{13,14,20}</p>
7.	Selection of study participants:	

	(a) Inclusion criteria:	All those who are above the age of 18 years and are permanent residents of the place with any of the following criteria will be included a) Indicate they are aware of being hypertensive b) are identified as having an average SBP of ≥ 140 mm Hg and/or DBP ≥ 90 mm Hg at the cross-sectional survey, subsequently attend their primary healthcare provider and are then formally clinically diagnosed with hypertension. Verification occurs by sourcing the medical record, contacting the healthcare provider or by confirmation of use of medication(s) for hypertension c) have an average BP of ≥ 140 mm Hg SBP and/or ≥ 90 mm Hg DBP during the baseline survey and then, at the time of recruitment to the intervention (or control), have their BP remeasured, and are found to still have an average BP of ≥ 140 mm Hg SBP and/or ≥ 90 mm Hg DBP.
	(b) Exclusion criteria:	Pregnant women will be excluded.
8.	Informed Consent:	Document attached
9.		
	Procedure for Measurements:	Details provided in Table 1 at the end of this document. Standardized clinical measurements will be collected as follows; arterial BP after the participant has sat quietly for at least 5 min. BP is measured at least three times at using the appropriate cuff size and a Digital Automatic Blood Pressure Monitor according to the WHO STEPS protocol. Measurement continues until two consecutive readings differ by
	Details of data to be collected:	Details provided in Table 1 at the end of this document
10.	Statistical details:	Data analysis will be based on intention to treat. The primary outcome, change in systolic blood pressure at six months, will be compared between the intervention and control arms using a generalized estimating equations approach using the robust variance and an MDEP working correlation matrix to take within-slum clustering into account, making assessment of normality of residuals unnecessary, with the individual change in systolic blood pressure the dependent variable. In secondary analysis, if there are some differences in risk factors for blood pressure between the individuals and slums in the intervention vs. control arms, confounding will be controlled for in secondary analysis using a multivariable GEE model. A similar approach will be taken with the other continuous secondary outcomes, such as BMI. Differences in the proportions of process outcomes, such as adherence, between the intervention and control arms at the end of follow-up, will also be compared using the GEE approach, with the

		log link function, taking clustering within slums into account with a working exchangeable correlation matrix. The level of statistical significance will be set at $p < 0.05$. FGDs will be audio-taped and will be transcribed verbatim. Themes will be identified and coded. The team will read the transcripts and notes and will reach a consensus. Any disagreements will be discussed regularly within the team to reach a consensus regarding theme coding. Sections with similar coding will be grouped according to the predetermined themes. Repeated themes will be marked as important in red font color. All the flagged statements will be put together and synthesized. Important quotations will be quoted which evoked spontaneous discussion, around which a lot of time is spent and have some emotional cues attached with.
11.	Study Requirements	
	Equipment required:	Attached as Budget in annexure
12	Study Budget	Attached as budget in annexure
13	Investigator Details	Dr Rakesh PS rakeshrenjini@gmail.com ; 9495537333; 8281315877
15	Designation of PI	Faculty-in-Charge Centre for Public Health, AIMS & Visiting Scientist, Harvard TH Chan School of Public Health, USA
16	Department	Centre for Public Health, AIMS & Department of Global Health & Population Medicine, Harvard TH Chan School of Public Health, USA
17	Date of Submission	19.05.18
18	Remarks by co-ordinator	

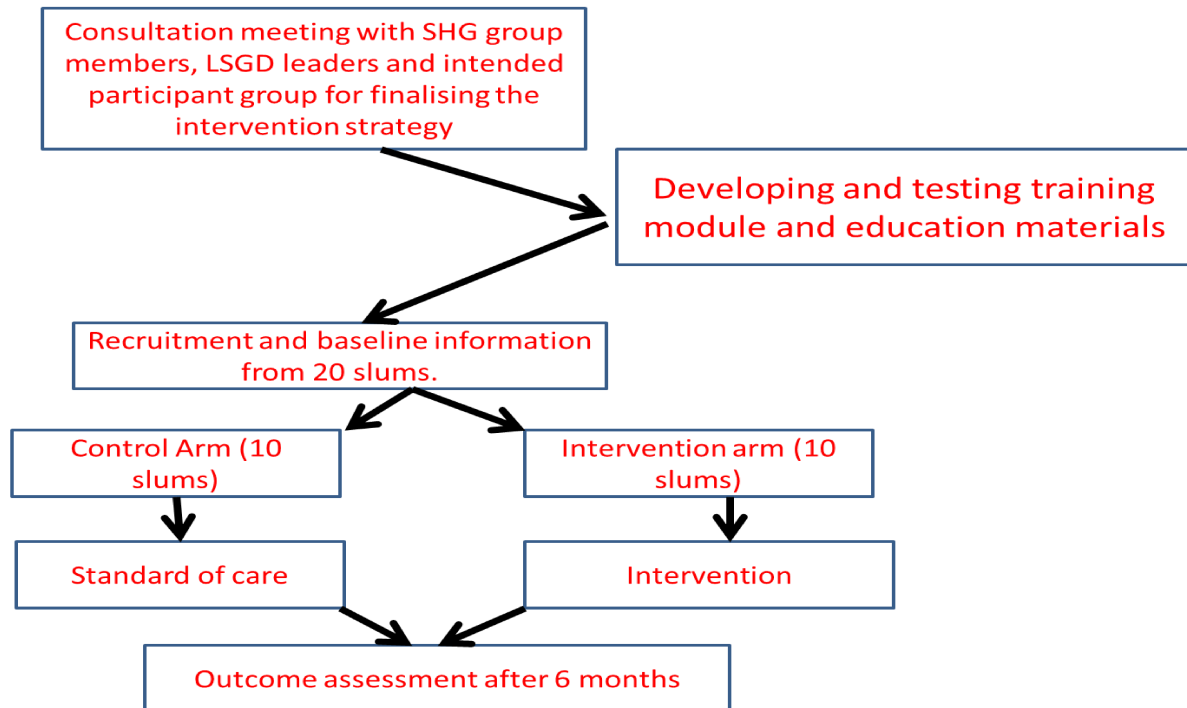
Fig 1. Steps in the study

Table 1. Outcome assessment, indicators, tools and time of assessment

Objective	Variables/Indicator	Measurement Tools	B*	FU*
Effectiveness in reducing blood pressure	Mean change in systolic blood pressure	Digital Automatic Blood Pressure Monitor	×	×
Hypertension self-care behaviour (diet, physical activity, smoking)	Mean change in BMI Smoking cessation rates Change in diet practices Mean change in HbA1c	Stadiometer and weighing scale WHO STEPS questionnaire Food frequency questionnaire HbA1c	×	×
Adherence to anti-hypertensive medication	Medication adherence score	Modified version of Morisky's 8 point adherence scale	×	×
Coverage	% of eligible people utilised various intervention	Survey results, Meeting reports		×
Acceptability, appropriateness, Feasibility	Qualitative Measurements- Perceptions of people, SHG members and LSGD leaders	FGD Guide		×
Fidelity		Checklist , Meeting reports, patient reports		×
Cost	Incremental cost per change in 1 mm Hg of blood pressure	Costing (Account books)		×

*B- Baseline, FU-Follow up at the End of the intervention

From
Dr Rakesh PS
Faculty-in-charge
Centre for Public Health

To
The Chairman
Institutional Review Board
AIMS

Through Head of the Department, Department of Public Health

Sub: Submission of a proposal for ethical committee clearance

Respected Sir,

We hereby submit a proposal titled “Effectiveness of a community-based education and peer support led by women self-help group members in improving the control of hypertension: an implementation research in urban slums of Kochi city, Kerala, India”. The study is being planned as part of my Lown Scholarship and has received an Award of 37750 USD from Harvard T H Chan School of Public Health.

Thanking you,

Dr Rakesh PS
18.05.18