BP-HOME MONITOR
Blood Pressure-HOME MONitoring
Intervention Trial and Outcomes Research

IMPLEMENTATION SCIENCE GROUP

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Significance and Impact

• In high income countries, home blood pressure management lowers blood pressure (BP) when compared to usual care\textsuperscript{1-4}.

• There is scarce data available about home BP management in low- and middle-income countries.

• Given the great burden of hypertension in low- and middle-income countries, identification of effective strategies to optimize BP management is critical.

\textsuperscript{1}Lancet 2010; 376: 163–72 \hspace{1cm} \textsuperscript{3}BMJ 2004;7458:145-148
\textsuperscript{2}JAMA 2014;312(8):799-808 \hspace{1cm} \textsuperscript{4}Hypertension. 2011;57:29-38
## SUMMARY OF PREVIOUS STUDIES

<table>
<thead>
<tr>
<th>Population</th>
<th>Intervention</th>
<th>Control</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>TASMINH2¹</td>
<td>Uncontrolled hypertension [BP&gt;140/90 mmHg]&lt;br&gt;Aged 35-85 without establish vascular disease</td>
<td>Patient self monitoring + drug titration</td>
<td>Usual care&lt;br&gt;Mean SBP Differences between groups&lt;br&gt;- 5.4 mmHg, 2.4 to 8.5; p=.0004&lt;br&gt;At 12 months</td>
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<tr>
<td>TASMIN-SR²</td>
<td>Uncontrolled hypertension [BP&gt;145/90 mmHg]&lt;br&gt;Aged&gt; 35  with high risk (CVD or DM)</td>
<td>Patient self monitoring + drug titration</td>
<td>Usual care&lt;br&gt;Mean SBP Differences between groups&lt;br&gt;- 9.2 mmHg, 5.7 to 12..7&lt;br&gt;At 12 month</td>
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</table>

¹Lancet 2010; 376: 163–72
²JAMA 2014;312(8):799-808
Research Question

• Can an intervention focused on patient home BP management (i.e., monitoring and medication titration) be implemented in low- or middle-income countries?
Conceptual Framework

Patient Level Factors
- Age
- Gender
- Education
- Hypertension awareness
- Duration of diagnosis
- Comorbidities
- Family structure
- Caregiver
- Access to healthcare

Provider Level Factors
- Age
- Practice type
- Location
- Size of practice
- Clinical inertia

Patient
- Medication adherence
- Intervention fidelity
- Quality of Life
- Self-efficacy

Provider
- Medication titration
- Intervention fidelity

Blood Pressure

Health system factors
- Availability of anti-hypertensive medication
- Insurance coverage of medications
- Organization of primary care system
- Availability of CHWs
Specific Aims

Specific Aim #1: To conduct a qualitative study of barriers, facilitators and context for home BP management in low- and middle-income countries.

Hypothesis: There will be unique contextual factors that will inform the design of a clinical trial (aim #2) of self management in low- and middle-income countries.
Specific Aims

**Specific Aim #2**: To determine the effect of home BP management on blood pressure levels and medication adherence

*Hypothesis*: Home BP management will optimize BP management (quicker dose titrations and improve medication adherence)

**Specific Aim #3**: Conduct a qualitative process evaluation to explore participant and health care team perceptions (acceptability, fidelity, satisfaction, challenges, and benefits) about the intervention and implementation process.
**STUDY DESIGN**

**Randomization**

- (Week 0) (Week 12)

**USUAL CARE – Control group**

- Clinic Visit (Month 3)
- (Month 6)

**HBPM+SELF TITRATION PLAN**

- (Month 3) Telephonic follow up
- (Month 6)

**QUALITATIVE RESEARCH**

- (Week 0)
- (Week 12)

↑ = Collection of study outcomes (BP measurements)

Phase 1 | Phase 2 | Phase 3
Phase 1: Qualitative study
Methods / Understanding the context on blood pressure management

• To conduct a qualitative study of barriers, facilitators and context of blood pressure self monitoring and medication self titration in low- and middle-income countries.

Focus groups, key informant interviews, practice context assessments

Beta testing of home blood pressure monitor

Beta testing of self titration protocols and materials
Interview guides standardized with input from local teams.

Conducted by local teams trained in qualitative data collection methods.

Adapt practice context assessment instrument with input from local teams.
Phase 2: RCT
Inclusion Criteria

• Consecutive consenting patients attending primary care/ cardiology clinics
- Aged > 18 years
- Established diagnosis of hypertension (or isolated systolic HT°) by a clinician and on an anti-hypertensive medication with clinic BP >140/90 despite treatment
- Ability or likely to return for 6 months follow up
Exclusion Criteria

• On 3 or more antihypertensive medications
• Acute stroke/MI (< 3 months since index event)
• Cancer, cognitive dysfunction, eGFR<30, any serious illness that might interfere with participation/ follow-up
• patient and caregiver who are illiterate (unable to read measures)
Outcomes

Primary -
1) Patient fidelity to the intervention
2) BP levels – Mean BP comparisons

Secondary -
1) Proportion of uncontrolled hypertensives in each arm
2) Difference in med adherence between I & C arms
3) Usage of and documentation in diaries
4) Cost-benefit analysis
5) Number of physician visits in each arm
6) Patients centered outcomes
7) Adverse events
Intervention Components

1) Home BP monitoring

2) Self titration of medications to BP targets

3) Patient diary – education and documentation

4) Both patient and carer are trained
Sample Size Calculation for Trial

- Two sample one sided
- 5 mmHg difference SD 15 mmHg
- 80% power / Type I error rate 5%
- N=112 /arm
- Drop rate 10%
- Final N= 123/arm= 246 patients

http://powerandsamplesize.com/Calculators/
Procedures - Baseline

• Validated, automated devices to be dispensed
• Out-patient based trained assistant to train the patient and at-least 1 carer on obtaining BP reading
• First set of readings entered into a translated patient diary
• Treatment and up-titration plan ratified by treating physician
Home Monitoring Scheme

• 2 morning readings, 5 mins apart, 1st week of every month

• Uptitration/ addition if any 4 readings every month exceed target ( > 130/85 mmHg)

• Patients report to care provider if SBP > 180 mmHg or SBP < 100 mmHg or heart rate < 50 bpm
Self Titration protocol

Population with well established diagnosis of hypertension

consent

Consent -

Consent +

CI for drug C, A or D

No

Usual care, 6 months FU

Home BP monitoring

1 h training on HBPM

Self titration protocol

SBP < 100 or > 180 or DBP > 110

Report to physician

135 < SBP < 180 or 85 < DBP < 110

Self titration C, A or D TBD according to guideline
Phase 3: Fidelity & Acceptability
AIM #3

• Qualitative process evaluation to explore participant and health care team perceptions (acceptability, satisfaction, challenges, and benefits) about the intervention and implementation process.

• Randomly select a subset of intervention participants for semi-structured interviews/focus groups.

• Interviews with health care teams.

• Fidelity assessment – patient diary assessment
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<td><strong>Data analysis, intervention evaluation, report writing</strong></td>
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## World Heart Federation BP MONITOR Budget

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<tr>
<th>Item details</th>
<th>2015</th>
<th>2016</th>
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<tbody>
<tr>
<td>Personnel expenses (including all benefits)</td>
<td>AED 4500,00</td>
<td>AED 4500,00</td>
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<tr>
<td>Equipment</td>
<td>AED 10000,00</td>
<td>AED 10000,00</td>
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<tr>
<td>Materials &amp; Supplies</td>
<td>AED 5000,00</td>
<td>AED 5000,00</td>
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<tr>
<td>Other items</td>
<td>AED 2000,00</td>
<td>AED 2000,00</td>
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<tr>
<td><strong>TOTAL</strong></td>
<td>AED 21500,00</td>
<td>AED 21500,00</td>
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**Personnel**

- **Project coordinator (50% effort, US$ 500 x 6 (months)***
- **Project Nurse (50% effort, US$ 250 X 6 (months)***

- He/She will coordinate overall research activities. He/She will deliver the lifestyle intervention material.

**Equipment**

- Seca weight scale (2@US$ 250)=500
- Seca height scale (2@US$ 200)=800

**Material and supplies**

- Study material (food diary, survey questionnaire, other), US$ 2,000,
- Expenses related to the focus group discussion US$ 3000
- Transportation and other related cost US$2000

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**Budget Proposal for One Site**
**Northern Areas of Pakistan**

Total Population: 1,000,000

Area: 72,495 square kilometers

Altitude of 1200 to 3200 metres

Impact of Home-based BP Monitor Site PT Syed M Shah

**Karimabad the Project Village**

Team of Nurses measure blood pressure

Interview and Examination at Home Setting
Thanks for your attention!!
Potential challenges and what we are doing to address them:

<table>
<thead>
<tr>
<th>Anticipated challenges</th>
<th>Proposed solutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multi-country data collection</td>
<td>Lead Research Team based at the country level</td>
</tr>
<tr>
<td>Small research grants</td>
<td>Local Research Teams to support some activities</td>
</tr>
<tr>
<td>Different field sites might not have same type of clinical setting, protocol and guidelines for management of hypertension</td>
<td></td>
</tr>
<tr>
<td>Communication between investigators based in different countries (geographical zones) might be difficult</td>
<td>Proposed monthly skype/conference call or face-to-face meeting once a year</td>
</tr>
<tr>
<td>Proposal might need to be approved by different IRBs taking long time</td>
<td></td>
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