# An Effective mHealth Service to Reduce Blood Pressure Without Adding Medications Through Personalized Automated Lifestyle Interventions

D.Cianflone*, G. Del Mauro^, T.Bordignon^, E.Colombo^, M.Fabi^, I.Viscone^^

**AMICOMED SA – Lugano - Switzerland**

## ABSTRACT

**Background**: Current guidelines require prescription of lifestyle modifications for all patients with prehypertension and hypertension. Lifestyle counselling is often provided with general rules but to be effective it requires a strong commitment from health professionals.

**Aim**: We evaluated the effect on blood pressure (BP) of a digital delivery personalized lifestyle-change (LC) program coupled with a BP -recording, -interpretation and -trend evaluation service (BT) or the BT alone as a digital plain diary, via App and website.

**Methods**: We studied 181 consecutive subjects (134M; 52±12years old) that joined LC voluntarily and unsolicited and 362 "double-control" matching subjects that only joined the BT. BT collects BP values, and after consistency-checks, feeds a proprietary CE-certified medical device algorithm to provide both actual BP interpretation and BP trend assessment. After collecting detailed clinical and lifestyle info LC provides a 3-month personalized lifestyle modification program for BP reduction. LC promotes regular BP measurements via digital engagement while BT alone doesn't. Progress on program implementation, continuity of BP measurement and BP changes were monitored: subsequent counselling was provided accordingly. BP changes were evaluated comparing BP values recorded at the beginning and at the end of the LC program.

**Results**: During the study period a total 15389 BP values were collected, subjects with discontinuous BP measurements during the LC program were excluded from evaluation. We hence analyzed the data of 129 LC subjects (mean persistence time 2.3 months) and 258 "double-control" matching BT subjects. Whilst non-significant differences were observed in BT subjects, we observed a significant reduction of BP in LC subjects at the end of the program for both systolic and diastolic BP: -4.7±1.2mmHg and -3.1±0.8mmHg, p<0.0001 (respectively).

**Conclusions**: This pilot study demonstrates that a personalized and actionable lifestyle change program prepared, delivered and monitored only through electronic means and coupled with a medical CE certified App for BP interpretation and trend analysis provides a strong and effective adjunctive tool for BP reduction.

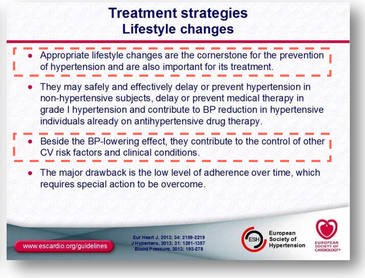
## BACKGROUND

### THERE IS A STRONG UNMET NEED

75% OF HYPERTENSIVES ARE SUB-OPTIMALLY TREATED

THE PROVEN LIFESTYLE CHANGES ARE HUGELY UNDERPRESCRIBED (<30%)

EVEN JUST A 2mmHg BP REDUCTION CAN HAVE A GREAT IMPACT ON RISK REDUCTION




## OBJECTIVES

To determine the **effects on blood pressure** of a **digital delivery personalized lifestyle-change** program coupled with a BP -recording, -**interpretation and -trend evaluation service** (BT) versus the BT alone as a digital plain diary, via **App and website.**



## METHODS & PATIENTS

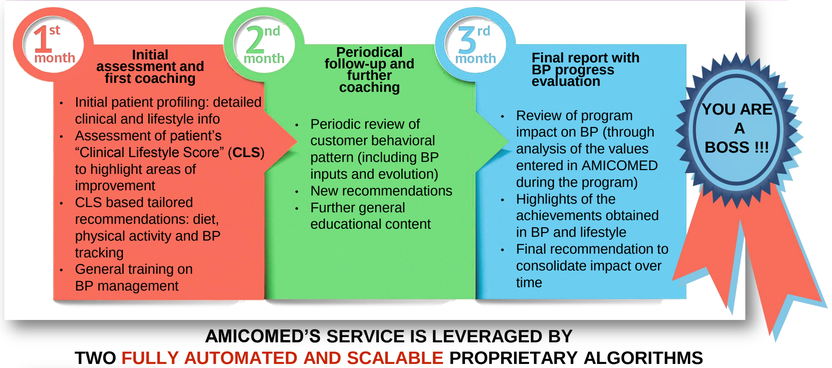
### REALTIME BP TREND ASSESSMENT SERVICE


- Real time **feedback** on each and **trend changes**
- **Visual alert** should potential clinical risk exist (e.g. very high BP)
- Ability to **separate trends** in different time bands
- Ability to distinguish between oscillation and trend
- Cloud-based storage and diary/graph accessible via App and website
- Customizeable objectives and reminders
- Connection with **Apple Health App**
- Bluetooth connected with iHealth BP monitors

### PERSONALIZED BP REDUCTION LIFESTYLE-CHANGE PROGRAM


- Web-based and fully digital
- Lifestyle changes: physical activity, dietary and BP tracking coaching program
- Highly personalized on patient's clinical and lifestyle information


### HOW DOES THE BP REDUCTION PROGRAM WORK ? – DURATION: 3MOS




### AMICOMED'S SERVICE IS LEVERAGED BY TWO FULLY AUTOMATED AND SCALABLE PROPRIETARY ALGORITHMS

PASCAL - provides instant assessment of BP evolution and variability. Patented and CE-marked as a class IIA medical device.

SMART PRESSURE - provides the personalized lifestyle coaching program for BP reduction

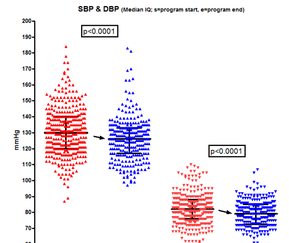
## SUBJECTS

- 181 consecutive subjects (134M; 52±12years old) that voluntarily and unsolicited joined the lifestyle change program
- 362 "double-control" (1:2) matching subjects that joined only BP trend assessment service
- (study conducted in Italy)

## RESULTS

- During the study period a **total 15389 BP values** were collected
- Subjects with discontinuous BP measurements were excluded
- Data of 129 program participant and 258 controls were analyzed
- 70% efficacy of the program, mean persistence 2.3 mos
- Controls did not obtain significant difference in BP values in a timeframe corresponding to their matched active program subjects

**Lifestyle change active program participants obtained a significant reduction of both systolic and diastolic blood pressure: -4.7±1.2mmHg and -3.1±0.8mmHg, p<0.0001 (respectively).**

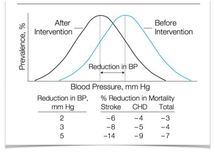



## CONCLUSIONS

This pilot study demonstrates that:

- A personalized and actionable lifestyle change program,
- prepared, delivered and monitored only through electronic means and coupled with
- medical CE certified App for BP interpretation and trend analysis…

**…provides a strong and effective adjunctive tool for BP reduction**




A 5 mmHg systolic BP reduction fosters a huge risk reduction (Whelton, JAMA, 2002)

## DISCLOSURES & DISCLAIMERS

* D.Cianflone: Co-Founder and Chief Scientific Officer – AMICOMED; Consultancy MIOL SA , Speakers Bureau: Lusofarmaco

^ G. Del Mauro^, T.Bordignon^, E.Colombo^, M.Fabi^: Employees at AMICOMED SA

^^I.Viscone: Consultant at AMICOMED SA

**The information presented in this abstract and all statements, evaluations, or data has not been evaluated by the Food and Drug Administration.**