DESIGNING A CLINICAL TRIAL PROTOCOL INCLUDING PHYSICAL AND MENTAL ACTIVITIES TO EXPLORE BLOOD PRESSURE DYNAMICS FOR MEDICAL DEVICE DEVELOPMENT

Objective

Cuff blood pressure monitoring is uncomfortable, limited for daily-routine and it provides sparse measurements in time. To enable continuous non-invasive monitoring, a cuffless blood pressure (BP) meter based on photoplethysmography (PPG) was developed and used in a first clinical trial. It aims at exploring the relationship between BP variations and optical features, including a wide range of intra-individual BP variations.

Design and method

The initial cohort of the clinical trial (IDRCB# 2022-A00123-40) includes five healthy subjects (1F/4M, age [37-60] years). Each subject is monitored with a medical-grade continuous BP meter, and a multi-sensing homemade platform integrating gold standard cuff measurements. The latter gathers PPG sensors, an ECG, a nasal cannula. The subject undertakes the following exercises: rest, static and dynamic strength exercises with a Pilates fitness ring, mental calculation, guided relaxation, and wall sit exercise. Each phase lasts 3 minutes, except the relaxation (10 minutes) and is followed by a 3-minute recovery.

Results

The impact of each activity is quantified by the range of mean arterial pressure (MAP), i.e. the difference between the initial value and the extremum during the interval. As the table shows, the highest median impact is achieved with the dynamic ring (+39 mmHg) and the wall sit (+33mmHg). The static ring and the stress occurred by the calculation exercise have a lower impact with an increase of 21mmHg and 19mmHg. Finally, the effect of the relaxation is verified with a median decrease of 13 mmHg.

	MAP [mmHg] Difference between start to extremum, median [min;max]
Dynamic ring	39 [22;57]
Wall sit	33 [16;66]
Static ring	21 [17;30]
Calculation	19 [-5;35]
Relaxation	-13 [-14;16]

Conclusions

These preliminary results (trial still running) show that building an accurate BP meter requires exploring the full range of BP in response to various physiological mechanisms. Therefore, it is necessary to combine relaxing and physical activities. Their impact vary among subjects and activities and illustrate that special care should be taken using real-time monitoring.