Implementation tells us more beyond pooled estimates—A secondary analysis of the GISMAL multi-country mHealth trial

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ABSTRACT

Background: The uptake of an intervention aimed at improving health-related lifestyles may be influenced by the participant’s stage of readiness to change a behaviour.

Objective: We aimed to conduct a secondary analysis of the GISMAL trial according to the levels of uptake of the intervention (dose-response) to explore i) outcomes by country, to verify the consistency of the trial’s pooled results stratifying by country, and ii) outcomes by each participant’s stage of readiness to change a given lifestyle at baseline. The rationale for this secondary analysis is motivated by the original design of the GISMAL study that was independently powered for the primary outcome, blood pressure, for each country.

Methods: We conducted a secondary analysis of a mHealth multi-country trial conducted in Argentina, Guatemala and Peru. The intervention consisted of monthly motivational phone calls by a trained nutritionist and weekly tailored text messages, over a 12-month period, aimed to enact change on four health-related behaviors: salt added to foods when cooking, consumption of high-fat and high-sugar foods, fruit/vegetable consumption, and practice of physical activity. Results were stratified by country and by the baseline’s stage of readiness to change (pre-contemplation/contemplation; preparation/action; or maintenance) of the participant. The exposure, intervention’s uptake, was how much of the intervention (<50%, 50%-74%, ≥75%) was received by the participant in terms of phone calls. Linear regressions were performed to model the outcomes of interest, presented as mean standardized values of the following: blood pressure, body weight, BMI, waist circumference, physical activity, and the four health-related behaviours.

Results: For each outcome of interest, and considering the intervention’s uptake, the magnitude and direction of the intervention effect differed by country and stage of readiness to change at
Among those on the higher intervention's uptake category, reductions in systolic blood pressure were only achieved in Peru whereas fruit/vegetable intake also showed reductions among those who were at the maintenance stage at baseline in Argentina and Guatemala.

Conclusions: Designing interventions oriented to improve health-related lifestyles may benefit from recognizing baseline's readiness to change and implementation uptake issues.

Trial registration: ClinicalTrials.gov NCT01295216. Registered 11 February 2011.

Key words: Lifestyle Risk Reduction, Behavior, Health Risk Behaviors, Clinical Trial; Argentina; Guatemala, Peru.
INTRODUCTION

Mobile health (mHealth) strategies have been increasingly used in public health research studies, some of them showing effective results in improving the profiles of traditional risk factors for non-communicable diseases,[1, 2] including in developing countries.[3-6] Most mHealth projects involve multifaceted complex interventions where the interplay of their components are key to determining an effect, thus requiring many more angles for their evaluation rather than a single indicator of effectiveness at the end of the trial.[7-10]

Multi-site trials are efficient in expanding enrolment targets.[11, 12] Multi-country studies, in addition, can provide heterogeneity in the diversity of settings where an intervention is being tested. It is well known that several individual and contextual factors may be directly related with the uptake and the implementation of the desired intervention.[13, 14] Yet, the effect of any given intervention conducted in a multi-site or multi-country study may differ by site or country, thus a single pooled effect estimate can cloud the true range of the intervention impact.

In addition to context, another major factor affecting the success of an intervention relates to the profile of participants. In biomedical and mechanistic research, the same chain of events applies to all participants. In the behavioral sciences, however, it is known that the targeting of certain behaviors may not be the same for each person, often requiring the acknowledgement and identification of the stage of readiness to change certain habits.[15, 16] The applicability of such readiness to incorporate changes towards healthier habits has been signaled for smoking cessation.[17, 18] An intervention may not have the same effect on people merely thinking of quitting an unhealthy habit compared to those already committed to quitting.
This GISMAL trial aimed to reduce blood pressure and to prevent the shift to hypertension in adult subjects with prehypertension in resource-constrained urban settings in Argentina, Guatemala, and Peru.[19] This trial used customized weekly text messages and motivational monthly phone calls aimed at the adoption of healthy lifestyles. Pooled results of the intervention showed reductions in weight but not in blood pressure after 12 months.[19] However, further scrutiny regarding its implementation is needed to better understand what works regarding mHealth, and its capability to support behavior change in real-world conditions.[20] Consequently, we aimed to conduct a secondary analysis of the GISMAL trial according to the levels of uptake of the intervention (dose-response) to explore i) outcomes by country, to verify the consistency of the trial's pooled results stratifying by country, and ii) outcomes by each participant’s stage of readiness to change a given lifestyle at baseline. The rationale for this secondary analysis is motivated by the original design of the GISMAL study that was independently powered for the primary outcome, blood pressure, for each country.
METHODS

Study Design

This is a secondary analysis using data collected in a mHealth randomized controlled trial (RCT), known as GISMAL. Results of the trial have been reported elsewhere. GISMAL was conducted in Argentina, Guatemala and Peru by targeting adult individuals with prehypertension with the primary aim to reduce blood pressure. The intervention arm received tailored phone calls and text messages to foster the adoption of a healthy diet and to improve physical activity profiles. Phone calls using the motivational interview method were delivered monthly by nutritionists in conjunction with weekly tailored text messages during a twelve-month period. These communications were tailored according to the stage of readiness to change that each participant had regarding the four hypertension-related risk factors the RCT aimed to improve, i.e. physical activity, fruit/vegetable consumption, decreased consumption of high-fat and high-sugar foods, and reduced salt intake. The control arm received usual care without any mHealth components.

Study Population

Subjects enrolled in the GISMAL trial were 30-60 years old males and females with prehypertension (systolic blood pressure between 120 and 139, diastolic blood pressure between 80 and 89, or both). Further inclusion criteria consisted of: i) not receiving medication for hypertension; ii) owning a mobile telephone; and iii) being able to read and understand text messages in Spanish. Childbearing women and people who reported having ever been diagnosed with hypertension, diabetes, or cardiovascular disease were excluded.
Variables Assessment

Three blood pressure measurements were taken in a sitting position after a 5-minute resting period using calibrated digital devices (Omron HEM-742INT, Omron Healthcare, Lake Forest, IL, USA); the mean of the last two readings was herein used. A digital scale (Omron SC-100/SECA 803) was used to measure bodyweight. Height was measured with the participant shoeless using a stadiometer, and waist circumference was assessed with a flexible non-elastic measuring tape. All other variables were assessed with standardized and validated questionnaires including a Food-Frequency Questionnaire[21] and the International Physical Activity Questionnaire (IPAQ) to assess diet and physical activity, respectively.[22]

Exposure Variable

For this study, the exposure variable was the uptake of the intervention, defined as the intervention receiving <50%, 50%-74%, or ≥75% out of the 12 planned intervention phone calls. The reference category was the control group of the original RCT, i.e. those who did not receive the mHealth intervention. The mHealth intervention also contemplated SMS reminders, but given how ubiquitous SMS are, paired with its difficulty to ascertain reception, it was decided not to consider them for the exposure categories. This was not considered a weakness in the ascertainment of exposure as SMS were only enacted following the completion of a phone call.

Outcome Variables

The original trial measured the following biological and behavioral risk factors assessed before and after the intervention: i) systolic blood pressure (mmHg); ii) diastolic blood pressure (mmHg); iii) weight (Kg); iv) BMI (Kg/m²); v) waist circumference (cm); vi) physical activity (METS/min per week); vii) fruit/vegetable consumption (number of daily servings); viii) high-sodium food intake (number of daily servings); and ix) consumption of high-fat and high-sugar foods (number of daily servings).
servings). For analytical purposes, these variables were treated as continuous and mean standardized, i.e. the mean was subtracted from the observed values, and then divided by the standard deviation.

For the outcomes by country analyses, we used the same nine outcomes. For the outcomes by baseline’s readiness to change analyses, we chose only four outcomes for illustrative purposes: two outcomes that were expected to increase following the intervention —fruit/vegetable consumption and physical activity—, and two outcomes that were expected to decrease —salt added when cooking and high-fat and high-sugar foods consumption.

Variables Used to Perform Stratified Analyses

Analyses were stratified by country (Argentina, Guatemala, and Peru) and by baseline stage of readiness to change regarding the improvement of a particular health-related lifestyle. There were three stages of readiness to change constructed based on the Transtheoretical Model of Health Behavior Change: a) pre-contemplation/contemplation; b) preparation/action; and c) maintenance. For the second aim of our study based on stage of readiness to change we used the four previously described health-related lifestyles, the first two expected to increase and the latter to expected to decrease post-intervention: i) consumption of fruits and vegetables; ii) physical activity profile; iii) salt added while cooking; and iv) intake of high-fat and high-sugar foods.

Statistical Analysis

Numeric variables were described with means and standard deviations (SD), while categorical variables were summarized using frequencies (%). Comparisons between numeric variables were assessed with the analysis of variance test (ANOVA). Linear regression models were conducted, with and without stratification by country and stage of change; intervention uptake was the independent variable and the biological and behavioral risk factors (mean standardized) were the
The regression models without any stratification were adjusted by country. The regression models stratified by country or stage of readiness did not include other variables than the exposure and outcome. Results from the regression models are presented as coefficients and 95% confidence intervals (CI). Analyses were conducted with STATA 13.0 (StataCorp, College Station, TX, USA).
RESULTS

At baseline, there were 637 participants (321 in the control group and 316 in the intervention group), 53.7% women, and the mean age was 43.4 (SD: 8.4) years. At the end of the study, 287 (89.4%) subjects remained in the control group and 266 (84.2%) in the intervention group. Among those who were initially in the intervention group, 40.5% (128/316) received <50%, 36.1% (114/316) received between 50% and 74%, and 23.4% (74/316) received ≥75% of the planned intervention phone calls. There were no differences in intervention dose by sex (p=0.052) or country (p=0.336). However, there were more young subjects (≤45 years) among those who received either <50% or between 50% and 74% of the intervention compared to those who received ≥75% of the intervention (p=0.001).

Supplementary Table 1 shows the means and standard deviations for each outcome of interest, so that the estimates of the figures can be computed in their original units (e.g., blood pressure in mmHg). The overall unstandardized estimates are also presented in all figures' footnotes.

Results by Country

Figure 1 shows the intervention effect for each of the biological and behavioral risk factors assessed by country among subjects who received the higher dose (≥75%) of the planned intervention phone calls. Regarding all nine metabolic risk factors, the magnitude of the intervention effect varied between countries. The intervention had an effect in the opposite direction than the expected whereby systolic blood pressure increased in Argentina and Guatemala. Those in the intervention group in Peru had a four-fold greater fruit and vegetable consumption than Guatemala and almost twice that of Argentina. Also, the reduction of fat and sugar food was almost two-fold higher in Guatemala and Argentina, than in Peru. Moreover, Peru
appeared to be only country where a reduction in systolic blood pressure was achieved. Overall, varying directions and magnitudes of effect were also observed among those who received <50% and 50-74% of the intervention (Supplementary Figures 1 and 2).

Figure 1: Assessed outcomes for subjects who received ≥75% of the intervention, overall and by country.
Results are presented as standardized means. These results are presented for subjects who received at least 75% of the intervention in terms of phone calls.

Arrows point at the expected direction of change having received the intervention. To compute each estimate in their respective units (e.g., blood pressure in...
multiply the standard deviation with the reported value in the figures and then divide by the mean (Supplementary Table 1). The overall estimate for systolic blood pressure equals to 123.45 mmHg, for diastolic blood pressure equals to 74.87 mmHg, for weight equals to 74.36 Kg, for BMI equals to 28.85 Kg/m$^2$, for waist circumference equals to 95.50 cm, for salt consumption equals to 0.40 servings/day, for high-fat and high-sugar foods consumption equals to 3.24 servings/day, for fruits and vegetables consumption equals to 2.70 servings/day, and for physical activity equals to 583.62 METS/min per week.
Outcomes by Participant’s Stage of Readiness at Baseline

Assessing the health-related lifestyle outcome of salt added when cooking (Figure 2) among those who received ≥75% of the intervention, the magnitude of the intervention effect varied according to stage of readiness to change at baseline. Specifically, the magnitude of the intervention effect was greater in those in the pre-contemplation/contemplation stage in Guatemala and Peru, than in those in the maintenance stage.

Figure 2: Intervention effect on salt added when cooking according to participant baseline stage of readiness status, overall and by country among those who received ≥75% of the intervention.
Results are presented as standardized means. These results are presented for subjects who received at least 75% of the intervention in terms of phone calls.

Arrows point at the expected direction of change having received the intervention.
Regarding fruit and vegetable consumption as a health-related lifestyle outcome (Figure 3), among those who received ≥75% of the intervention, the magnitude and the direction of the intervention effect differed by country. In Peru the direction of the intervention was the same according to stages of change, with those in the maintenance stage showing the largest effect. On average, as well as in Guatemala and Argentina, for those in the maintenance stage of readiness to change at baseline, the intervention effect observed was in the opposite direction than expected, whereby fruit and vegetable consumption decreased.

Figure 3: Intervention effect on fruit and vegetable consumption according to the participant baseline readiness to change status, overall and by country among those who received ≥75% of the intervention.
Results are presented as standardized means. These results are presented for subjects who received at least 75% of the intervention in terms of phone calls.

Arrows point at the expected direction of change having received the intervention.
The results of the intervention exposure on the other two health-related lifestyle factors are shown in Supplementary Figures 3 and 4, respectively. Regarding the consumption of high-fat and high-sugar foods (Supplementary Figure 3), Argentinians in the pre-contemplation/contemplation stage of readiness to change at baseline had an increased consumption that was in the opposite direction as expected. Finally, regarding the health-related lifestyle outcome of physical activity (Supplementary Figure 4), for those in Guatemala and Peru in the maintenance stage of readiness to change at baseline, they decreased their physical activity profile that was also in the opposite direction as the expected.
DISCUSSION

Our secondary analysis of the GISMAL trial shows that variations in the effect by country and by stage of readiness to change at baseline. Acknowledging that the original trial was originally independently powered for the primary outcome, blood pressure, for each country, we found such positive trial’s effect on systolic blood pressure only in Peru. Considering the intervention’s uptake, the magnitude and direction of the intervention effect differed by country and stage of readiness to change at baseline. For example, among those on the higher intervention’s uptake category, reductions in systolic blood pressure were only achieved in Peru whereas fruit/vegetable intake also showed reductions among those who were at the maintenance stage at baseline in Argentina and Guatemala. These findings call for additional considerations when conducting complex multi-country or multi-site behavioral interventions. For example, when planning future interventions, readiness to change could be a parameter to ponder in sample size calculations, stratification, among other considerations at the design stage of the study.

We reported a greater magnitude of the intervention effect among those in the Pre-Contemplation/Contemplation stage of readiness to change at baseline or, in other words, those who, apparently, had the least predisposition to uptake healthy lifestyles. Those in the Pre-Contemplation/Contemplation stage may have been unaware of the health risks of certain lifestyles, or how to make their lifestyles healthier. We can speculate that the intervention provided to them with the necessary amount of interaction, information and tools to improve their lifestyles. In so doing, those in the Pre-Contemplation/Contemplation stage were probably keener to engage with and uptake healthier habits compared to those in the other stages of readiness to change. Moreover, people in the Pre-Contemplation/Contemplation stage had more room for improvement in terms of lifestyle behaviors, so even small changes in
adoption of healthier lifestyles would have had a greater health impact than similar changes to be observed amongst those in other stages of readiness to change.

Result from this secondary analysis align with recommendations to better understand the role of technology in enacting and sustaining behavior change.[24] The results observed in our study signal towards tailoring future study's interventions to specific stages of readiness to change. The duration and multi-pronged design of the GISMAL mHealth trial, conducted over a 12-month period targeting multiple behaviors, provides more insights into short-term action and long-term behavior change. We did not explore predictors of engagement or habituation, which opens additional venues to understand short- and long-term effects of future mHealth behavior-oriented studies. Additional caution should be placed on the mode of delivery, as it should not be assumed that all different platforms to deliver technology-based interventions would have the same adoption, engagement over time, and expected effects in the same order of magnitude.[25]

From an implementation perspective, the varying results observed may have been due to differences in a number of implementation research-related indicators.[20] Among the strengths of our study lies the multi-country deployment of the same intervention allowing for this mHealth intervention to operate in different "real-world" settings. Additional strengths rely on the objective ascertainment of the intervention’s uptake, which used completed phone calls made by the nutritionists, thus providing a pragmatic approach to evaluate the implementation of mHealth strategies without the need to rely on SMS only. Fidelity was enacted before and during the conduction of the trial through a standardized approach using the same training and supervision procedure for the nurse calls, the same algorithm to enact SMS delivery, and training of fieldworkers.[19] Appropriateness was anticipated through a qualitative study and a theory-driven development of the SMS involving health communication and psychology experts before the intervention.[26] We do not have information around acceptability of the
intervention, which may have provided a richer picture of implementation issues, but this indicator is in part covered by the intervention's uptake over its 12-month duration, thus permitting a partial picture of acceptability from the end-user's point of view.

Some limitations include the fact that some outcomes were self-reported, such as a physical activity or food consumption. Also, the results warrant cautious interpretation because of the lack of statistical power for sub-group analyses for all the outcomes. As the overall goal of this paper was to identify signals in the effect of the intervention across countries and stage of readiness to change at baseline, we did not aim to assess such potential variations in clinically relevant units, e.g. transforming standardized mean values into mmHg for blood pressure.
CONCLUSIONS

In summary, the results of this multi-country mHealth intervention trial, originally aimed at reducing the progression of prehypertension to hypertension by improving health-related lifestyles, show that outcomes do vary by country and according to the participant stage of readiness to change a specific behavior at baseline. This information will be of utmost utility when designing future studies and provides important pragmatic lessons around implementation issues, emphasizing indicators amenable to be monitored.
ABBREVIATIONS

Randomized controlled trial: RCT

International Physical Activity Questionnaire: IPAQ
DECLARATIONS

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Conflict of interests

The authors declare that they have no competing interests.
Ethics approval and consent to participate

The protocol for the original RCT was independently reviewed and approved by Institutional Review Boards in the three participating countries: Hospital Italiano de Buenos Aires (Argentina), Institute of Nutrition of Central America and Panama (Guatemala), Universidad Peruana Cayetano Heredia (Peru). The original RCT protocol was also reviewed and approved by the RAND Corporation, Santa Monica, CA, USA. Written informed consent was provided by all participants. The trial is registered at ClinicalTrials.gov (NCT01295216).

Authors’ contribution

JJM conceived the research idea. RMC-L, SSJ and JJM designed the analysis plan and the outline of the study. RMC-L conducted the analysis and wrote the first draft of the paper. All authors gave major comments and edited the paper. All authors approved the final version.
REFERENCES


39114. Medical Research Council (MRC). Developing and evaluating complex interventions. URL: https://www.mrc.ac.uk/documents/pdf/complex-interventions-guidance/. (Archived by WebCite® at http://www.webcitation.org/6xWsN5QbA)


Supplementary Table 1: Means and standard deviations for each outcome variable at 12 month of the intervention, overall and by country.

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<th>Variable</th>
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<th>Peru</th>
<th>Argentina</th>
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<td>N=533</td>
<td>N=170</td>
<td>N=193</td>
<td>N=190</td>
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<td>122.15 (10.81)</td>
<td>121.18 (10.58)</td>
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<td>Diastolic blood pressure at 12 months (mmHg)</td>
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<td>N=170</td>
<td>N=193</td>
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<td>71.86 (8.05)</td>
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<td>Weight at 12 months (Kg)</td>
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<td>N=191</td>
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Results are presented as mean (standard deviation). P-value of the ANOVA test for each outcome among countries.
Supplementary Figure 1: Assessed outcomes for subjects who received <50% of the planned intervention phone calls, overall and by country.

Results are presented as standardized means for subjects who received less than 50% of the intervention in terms of phone calls. Arrows point at the expected direction of change having received the intervention.
Supplementary Figure 2: Assessed outcomes for subjects who received 50%-74% of the planned intervention phone calls, overall and by country.

Results are presented as standardized means for subjects who received between 50% and 74% of the intervention in terms of phone calls. Arrows point at the expected direction of change having received the intervention.
Supplementary Figure 3: Intervention’s effect on high-sugar and high-fat food consumption according to the participant’s baseline readiness status, overall and by country.
Results are presented as standardized means. These results are presented for subjects who received at least 75% of the planned intervention phone calls. Arrows point at the expected direction of change having received the intervention.

Supplementary Figure 4: Intervention’s effect on physical activity according to the participant’s baseline readiness status, overall and by country.
Results are presented as standardized means. These results are presented for subjects who received at least 75% of the planned intervention phone calls. Arrows point at the expected direction of change having received the intervention.