

論文内容要旨

Awareness Development and Usage of Mobile Health Technology among Hypertensive Individuals in a Rural Community of Bangladesh: A Randomized Controlled Trial.

(バングラデシュ農村地域における高血圧患者の意識向上とモバイルヘルステクノロジーの使用：無作為化比較試験)

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This study is a community-based randomized controlled trial (RCT) for hypertensive individuals to increase their awareness and behavior changes by using mobile health technology in a rural community of Bangladesh.

Introduction

Non-communicable diseases (NCDs) are the leading causes of death globally and among the NCDs, hypertension (HTN) is a major modifiable risk factor. Currently, the prevalence of HTN is higher in low-and middle-income countries. Moreover, the comorbidities related to HTN may cause the greatest morbidity burden if left untreated especially in low-resource settings. Therefore, continuous long-term BP monitoring including medication adherence is needed. With regards, the two-way short text messaging communication stated as a commonly used approach that can develop awareness and improve an individual's self-management about HTN. Therefore, we conducted this study. The purpose of the study was to develop awareness and knowledge in order to enhance lifestyle behavior changes among hypertensive individuals in a rural community of Bangladesh by using mobile text messaging and in-person health education.

Methods

A single-center, prospective randomized (1:1), open-label, parallel-group study was conducted in a rural community of Bangladesh involving hypertensive people. The intervention period was 5 months and the total study duration was 12 months. This study was conducted between August 2018 and July 2019. Hypertensive individuals were identified from a tertiary level health facility by reviewing the registered clinician's prescriptions and hospital logbook, and by door-to-door visit. Purposive sampling method was used and the eligibility criteria were hypertensive individuals of either sex aged 35 years or older, had 1-5 years of schooling, resided within a radius of 3 miles from the tertiary hospital, decided to stay in the community for at least five-month, had a personal cell-phone or access to a shared-phone, and willing to participate in the study.

The Intervention Group received 5 months in-person health education along with health education booklet and text messaging to develop awareness and knowledge and motivate for behavior changes. *The Control Group* received the same health education booklet as intervention group during enrollment. *For both Groups*, participants were followed up for 5 months (first month twice, and once for the rest).

The primary outcome was the evaluation of self-reported lifestyle behavior changes (salt intake, fruits intake, vegetables intake, physical activity, blood pressure (BP) monitoring,

and body weight monitoring). The measurement tool was a Likert-type response scale. *Secondary outcomes* were (1) the actual salt intake and dietary salt-excretion, (2) BP value, (3) blood glucose level and (4) urinary protein excretion for checking comorbidities, and (5) quality of life measured by EQ-5D-5L questionnaire.

Results

Of the 450 individuals who met the eligible criteria, 420 participants consented to participate in the study (consent rate, 93%). Total 8 participants dropped out at the end of the study. In total, the mean age was 47.1 ± 8.4 years; 86% were female, and 82% were housewives.

Primary Outcome (Behavior Change): The adherence rates were significantly higher among the control group regarding salt intake behavior and physical activity behavior (the difference was 9% between the two groups), and very little differences were observed in other behaviors. The salt intake and fruits intake behavior showed significant improvement in both groups ($P < .001$). After the intervention, physical activity reached to “Everyday/week” and continued until the study end ($P < .001$, both groups). BP and body weight monitoring status per month were increased up to 1 month but decreased afterwards. The difference was statistically significant in both groups ($P = .001$).

Secondary Outcomes: Study findings showed significant chronological changes in urinary salt concentration between the groups ($P = .01$). In case of food salinity, the control group showed ample drop ($P < .001$), compared to the intervention group ($P = .001$). Systolic BP (SBP) and diastolic BP (DBP) were significantly chronologically decreased in both groups ($P < .001$). In the case of QOL, both groups were significantly improved ($P < .001$).

Discussion

Among the study population, no significant differences were found in baseline demographic characteristics. Regarding primary and secondary outcomes, both groups improved significantly. Unexpectedly, we found in-person health education only (Control group) was more effective rather in-person health education with text messaging (Intervention group). We concluded that in-person education (community health workers’ home health care provision) might be one of the major factors for the improvement of outcomes.

Conclusions

The results of the present study could not show the effectiveness of text messaging along with in-person health education, rather in-person health education alone provided better impact on behavior changes. From this study results, we may suggest that in-person health education requires integration of home health care provision as a major factor for the improvement of outcomes as well as self-management behavior. Besides, it can be recommended that the more relevant and timely interactive messages can be sent to

increase the effectiveness. Finally, the study recommends organizing community awareness to create 'low-salt culture' and educate the family members.

本研究は、バングラデシュ農村地域で実施した、モバイルヘルステクノロジーを活用した、高血圧患者の意識向上と行動変容を狙った、地域を基盤とした無作為化比較試験である。

【背景】 高血圧は、心血管疾患等の合併症を引き起こす非感染性疾患であり、バングラデシュでは高血圧の有病率は増加している。その一方で、高血圧とその合併症発症の低減に向けた保健指導の効果を評価した研究は限られる。本研究では、農村地域でも保有率の高い携帯電話を活用した双方向性ショートテキストメッセージ (SMS) と、家庭訪問による個別対面保健指導を通して、バングラデシュ農村地域の高血圧患者が疾病改善に向けた自己管理行動を獲得することを目的とした。意識向上に向けては、日本で開発された尿中塩分測定器や食事の塩分濃度を測定するデジタル塩分測定器を用いた。また、家庭訪問での健康チェックを容易にする機器「ポータブルヘルスクリニック」を活用した。

【方法】 研究実施地域に在住する高血圧の診断のある 35 歳以上の住民で、携帯電話または共有電話へのアクセスが可能な者を対象に、前向き無作為化 (1 : 1)、非盲検、並行群間試験を実施した。介入期間は 5 か月である。標本数は、各グループ 210 人に設定した。対照群には、通常を受診に加え、不利益がないよう、初回面談時に、訓練を受けたコミュニティ・ヘルス・ワーカー (CHW) による身体計測、血液・尿検査・塩分摂取量の測定を行い、加えて、高血圧に対する保健指導 (DASH Diet を基盤) を行った。介入群には、対照群の内容に加え、行動の変化への動機付けと継続を強化するために、テキストメッセージを 5 ヶ月間、定期的に送信した。**主要評価項目**は、自己申告による生活行動の変化 (塩分摂取、果物・野菜摂取、身体活動、血圧と体重のモニタリング) で、リッカート尺度を用いて評価した。**副次評価項目**は、実際の塩分摂取量と尿中塩分排泄量、血圧値、血糖値、尿中タンパク及び QOL (EQ-5D-5L) 尺度を用いた。

【結果】 適格基準を満たした 450 人のうち、420 人の参加同意を得て (同意率、93%)、無作為に介入群 (n=209) と対照群 (n=211) に割付けた。介入中に 8 人が脱落し、最終分析対象は 412 人である (平均年齢 47.1±8.4 歳、女性 86%、主婦 82%)。主要評価項目 (介入終了時点の生活行動の変化率) は、塩分摂取行動と身体活動行動に関して対照群の方が有意に高かった (2 群間差は 9%)。一方で、群内においては、塩分摂取行動と果物摂取行動は、両群共に有意な改善を示した ($P < .001$)。介入後、身体活動は両群共に約 95%が毎日実施に達し、研究終了まで行動は継続した ($P < .001$)。定期的な血圧と体重のモニタリング行動は 1 か月までは増加したが、その後は減少した。また、副次評価項目においても、両群共に尿中塩分排泄量、食物塩分摂取量、血圧、QOL について有意な改善を示した。

【考察と結論】 両群ともに保健指導の効果は大きく、統計的に有意に改善したが、テキストメッセージの追加による効果は観察されず、個別家庭訪問による丁寧な保健指導のみによる効果の方が大きいことが結論づけられた。テキストメッセージは参加者の行動とは無関係に定期的に発信され、個別化されていなかったことが、効果に結び付かなかったと考える。

塩分摂取量を直接示し、対面による丁寧な個別保健指導は、教育レベルが低い農村地域におい

でも有効である。その一方で、モバイルヘルステクノロジーを有効に活用するためには、タイムリーで、状況に対応したメッセージの送信の必要性が示された。