博士論文（要約）

Feasibility of a smartphone-based self-management support system with enhanced goal setting and automated feedback focusing on the number of steps: System development, and a before-after study with workers with high blood pressure

（歩数増加のための目標設定支援・自動フィードバック機能を強化した自己管理支援 ICT システムの開発と血圧高値の労働者を対象とした前後比較試験）

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論文の内容の要旨

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Aims

We developed behavioral theory-based new functions for increasing the number of steps added to an extant smartphone-based self-management support system (DialBetics) (Chapter 1). The before-after study aimed to evaluate the feasibility and the usefulness of an intervention using the new system (DialBetics Step) to increase the number of steps in workers with high blood pressure (BP) and to describe necessary improvements of new functions from users' points of view (Chapter 2).

Chapter 1: System development

Methods

System development comprised four phases: 1) deciding the overall view of new functions, 2) creating contents and algorithms, 3) implementing the new functions in DialBetics by outsourcing, and 4) pretesting. In Phases 1 and 2, the author reviewed the literature and had continuous discussions within the interdisciplinary research team. In Phase 4, the author and seven other healthy adults used DialBetics Step to test the user interface and the accuracy of new function algorithms.

Results

Based on Social Cognitive Theory, we developed an enhanced goal setting and automated feedback functions to increase the number of steps. We hypothesized that the new system would enhance users' self-efficacy for walking by supporting their self-regulation, resulting in an increase in daily steps. We also included information delivery functions to provide users with knowledge and skills on how to perform the behavior. The target population of the new system was defined based on the stages of change in the Transtheoretical Model as people in the contemplation and the preparation stages of increasing daily steps.

Increasing the number of steps in DialBetics Step was divided into three functions: 1) self-monitoring, 2) information delivery, and 3) enhanced goal setting and automated feedback. DialBetics

already has functions to record daily steps, blood glucose, BP, body weight, and dietary information and to show them as a list and a graph (function 1). When starting the use of the new functions, users set their goal number of daily steps based on their baseline data and make an action plan to achieve their goals by themselves (function 3). After recording steps every day, users can get positive feedback on their goal achievement (function 3). They also receive either positive feedback on favorable behavior (function 3) or individualized advice to promote physical activity (PA) (function 2) according to their goal achievement. Once a week, users receive weekly evaluation messages on their number of steps, blood glucose, BP, and body weight (function 3). Then they re-set their step goals based on goal achievement in the previous week and modify their action plans (function 3). When goal achievement is difficult, users identify barriers to walking and ideas for solutions as a part of the action plan (function 3).

Chapter 2: Before-after study

Methods

Design: We conducted a single-arm before-after study in cooperation with an enterprise-based health insurance society in Tokyo. We originally designed the short-term study to evaluate the feasibility and the usefulness of the intervention for six weeks of using the new functions of DialBetics Step. However, participants ended up using the functions for a total of 24 weeks as part of a health promotion program in the workplace setting.

Participants: Employees of four private enterprises in the service industry whose systolic BP had been 140 mmHg or higher at a workplace health checkup in the fiscal year 2017 were included in this study. Candidates who judged themselves to meet the three entry criteria (not walking enough in general, but being willing to increase PA through walking, and able to engage in moderate PA) applied for participation.

Interventions: All participants attended a two-hour group session that included a lecture on lifestyle-related diseases and general recommendations for diet and exercise (conventional intervention). Participants then used DialBetics Step for 26 weeks, starting with a two-week baseline period in which they used only the self-monitoring function (conventional intervention) under their normal lives for baseline data collection (T0). They measured BP twice a day and body weight once a day. Some participants also measured blood glucose levels once or twice a day. All participants wore a tri-axial accelerometer (Terumo; MT-KT02DZ) during all waking hours to count daily steps. They recorded measured data immediately and recorded the accelerometer data into the system every night. They also input their diet every day and input any exercise not counted by the accelerometer. After the two-week baseline period, all participants used all functions of DialBetics Step for 24 weeks (intervention period).

Primary outcome: The primary outcome was the change in the mean number of daily steps recorded in the system between the baseline period (T0) and Week 5–6 of the intervention period (T1). We also compared mean daily steps measured by participants' own devices for a week between before intervention (T-1) and T0 to assess the potential effects of the conventional intervention.

Secondary outcomes: We assessed changes in self-efficacy and frequency of self-regulation and self-management behavior related to PA in the questionnaires at the time of group session (T-1) and after Week 6 of the intervention period (T1). We also evaluated changes in biomedical characteristics: home BP recorded in the system (T0 vs. T1), body weight, body mass index (BMI), and visceral fat area measured at the hospital (T-1 vs. T1), and levels of hemoglobin A1c, fasting blood glucose, triglyceride, high-density lipoprotein (HDL) cholesterol, and calculated low-density lipoprotein (LDL) cholesterol from blood examination (T0 vs. T1). Participants answered another questionnaire to evaluate the subjective usefulness and user-friendliness of DialBetics Step.

Sample size: We assumed a clinically meaningful change in the number of daily steps to be 1,000. Standard deviation (SD), based on a previous study of DialBetics, was estimated to be 1,800. We calculated the sample size for efficacy analyses to be 28 to detect 0.55 SD of change, with 80% power at the 5% significance level.

Statistical analyses: Changes in outcomes were analyzed by a paired *t* test or the Wilcoxon sign rank test. We also calculated the effect size. We conducted two types of post hoc analyses to explore factors related to an increase in the number of daily steps (T1-T0). First, we examined associations between baseline characteristics of participants and the change in the mean number of daily steps using Student's *t* test, analysis of variance, or Pearson's correlation coefficient. Secondly, we conducted subgroup analyses of secondary outcomes by the change in the mean number of daily steps (the "increasing group," in which participants increased steps by 1,000 or more per day vs. the "not increasing group").

Workshop and interviews: After the six weeks of the intervention period, participants attended a two-hour workshop at the University of Tokyo Hospital consisting mainly of group discussion (three to five participants per group) on improvements needed in new functions. The workshop was designed and conducted as a Global Design Workshop (GDWS) of the Graduate Program for Social ICT Global Creative Leaders (GCL) at the University of Tokyo. We performed qualitative content analysis to derive themes of needed improvements from users' points of view, especially participants in the "not increasing group."

Results

Participant flow and baseline data: Of 259 eligible employees, 34 (13.1%) provided written informed consent and received interventions. We included 30 participants in the theoretical target (male: 63%, mean age: 53 years old, mean clinic BP: 148/98 mmHg, and mean BMI: 23.5 kg/m^2) in efficacy analyses. None of the participants dropped out from system use until Week 6.

Primary outcome: The mean number of daily steps significantly increased at T1 (10,142 at T0 vs. 11,492 at T1) with a medium-to-large effect ($p = 0.0011$, Cohen's $d = 0.66$). Seventeen participants (57%) increased by 1000 or more steps per day ("increasing group"). On the other hand, mean daily steps did not change significantly between T-1 and T0 (9,435 vs. 9,641, n = 9).

Secondary outcomes: The total score, the scores for almost all factors of self-regulation, and the scores for almost all factors of self-management behavior related to PA significantly increased at T1. However, self-efficacy and home BP did not change significantly. Of the other biomedical characteristics, body weight and BMI decreased and HDL-cholesterol increased significantly at T1. Users rated the self-monitoring function, the goal setting for daily steps, and weekly feedback as more useful and user-friendly than the action planning and messages after recording daily steps.

Post hoc analyses: Male participants and those whose BMI > 22 and < 25 (high normal) were likely to increase their number of daily steps compared to other participants ($p = 0.02$ and $p = 0.09$, respectively). Scores for self-monitoring, goal setting, and relapse prevention in self-regulation were likely to increase only in the "increasing group," indicating the relationship between changes in self-regulation and that in the number of steps.

Needed improvements in new functions: Two themes were derived from group discussion with participants in the "not increasing group." First, they required more detailed information on other PA parameters measured by the accelerometer, a desirable goal for PA, and the effects of increasing the number of steps. Second, participants suggested a need for support in setting and achieving a more challenging goal (e.g., receiving more specific feedback or information to increase their confidence).

Conclusions

We developed a novel smartphone-based self-management support system with enhanced goal setting and automated feedback functions to increase the number of steps. Workers with high BP increased their number of daily steps by using the new functions of DialBetics Step for six weeks, although they had already reached the desired number of steps before using them. The participants also increased the frequency of self-regulation and self-management behavior related to PA compared to before the intervention; the former was associated with the change in the number of steps during system use. The intervention using DialBetics Step might be feasible and useful in increasing the number of steps through the enhancement of self-regulation. After the improvement of the system by tailoring it to the participant's needs, we plan to conduct a randomized controlled trial comparing the new system and the system with only the self-monitoring function and the information delivery functions in order to examine the effectiveness of enhanced goal setting and automated feedback functions.